SUPPLY, PROCESSING, AND DISTRIBUTION (SPD) OPERATIONAL REQUIREMENTS

1. REASON FOR ISSUE. To revise Department of Veterans Affairs (VA) Handbook 7176, Supply, Processing, and Distribution (SPD) Operating Requirements, formerly contained in VA Manual MP-2, subchapter E, 108-76. This handbook has been revised in accordance with the VA Directives Management System, which requires review and update of directives and handbooks every 3 years to ensure that obsolete material is rescinded. VA Handbook 7176 was initially published April 5, 1996.

2. SUMMARY OF CONTENTS/MAJOR CHANGES:

a. This handbook provides mandatory procedures pertinent to the operational requirements and responsibilities of all VA SPD activities.

b. SPD Handbook H-90-1, dated April 1992, has been consolidated into this handbook.

c. Part and section numbers have changed.

d. The term “Chief, SPD” will refer to any program official who is responsible for the management of SPD functions within a medical center or clinic.

e. The term “SPD Desk Guide” will refer to the hard binder used to file all SPD-related directives, handbooks, manuals, and operating instructions.

3. RESPONSIBLE OFFICE. Deputy Assistant Secretary for Acquisition and Materiel Management (049).

4. RELATED DIRECTIVE. VA Directive 7176.

5. RESCISSION. VA Handbook 7176, dated April 5, 1996, and SPD Handbook H-90-1, dated April 1992, in their entirety.

CERTIFIED BY:

John A. Gauss
Assistant Secretary for Information and Technology

BY DIRECTION OF THE SECRETARY OF VETERANS AFFAIRS:

D. Mark Catlett
Principal Deputy Assistant Secretary for Management

Distribution: RPC 7006
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PART 1. ORGANIZATIONAL STRUCTURE

1. 101 STATEMENT OF MISSION. Supply, Processing, and Distribution (SPD) is a section of the medical center that is dedicated to the receiving, storage, and distribution of medical supplies and the decontamination and sterilization of reusable medical supplies and equipment. The degree of specialized knowledge, as well as the nature and variety of skills required in the management of the SPD section, dictates a maximum delegation of authority to the Chief, SPD. The Chief, SPD, is the program official responsible for management of the supply, processing, and distribution functions within the medical center or clinic. This individual must exercise independent judgment in all technical and most managerial aspects of the function.

a. Operations vary greatly from facility to facility; however, program emphasis should be directed toward a total SPD support concept, enabling medical practitioners to administer the highest standard of healthcare with the resources available.

b. SPD optimizes its support of the medical facility by providing integrated material management and ensuring a continuous flow of processed sterile and non-sterile supplies, instruments, and equipment to all points of use. Similarly, return of reusable soiled items to SPD is handled in a manner conducive to economical and efficient processing for future use.

c. The objectives of SPD will be to provide centralized total supply support of the medical center's patient care programs, while assuring appropriate aseptic conditions, economy of operation, and consistency in processing, storing, and distribution, all under strictly controlled conditions. The major goal of SPD is to allow the professional medical staff every opportunity to concentrate on direct patient care.

2. 102 0RGANIZATION/FUNCTION. SPD is organized into sections, each with a defined scope of activities and an organizational structure of its own. (See Part 15, Illustration.)

3. 103 SUPERVISORY RESPONSIBILITIES

a. In accordance with VHA Directive 99-024 and VHA Handbook 1761.2, Standardization of Supplies and Equipment, the VHA Chief Financial Officer (CFO) is responsible for establishing User Groups, as appropriate, for the purposes of identifying items for system-wide standardization. The VHA CFO will coordinate review and concurrence of final user group recommendations through the VHA Chief Network Officer and appropriate VHA Chief Officers. The VHA CFO and Deputy Assistant Secretary for Acquisition and Materiel Management (DAS/A&MMS) (049) will ensure that procurement action will be effected by the appropriate contracting office.

b. The Chief, SPD, has supervisory responsibility over the organization known as SPD. The nature of the work environment places the Chief, SPD, in a key position requiring tact, diplomacy, and reliable decision-making abilities to carry out assigned responsibilities. The Chief, SPD, will be certified by completing the VA SPD Certification Program and maintaining certification requirements while in the position. The responsibilities of the Chief/Assistant Chief, SPD, include:

(1) Seeking guidance and direction from upper-level management at the facility in the form of general policy statements and planned objectives relating to general support activities.

(2) Exercising independent judgment in aligning administrative controls and communicating, planning, training, and directing the functional activities of SPD within broader medical center goals and policies. Independent judgment is exercised in all technical matters within the scope of the SPD functional activity.

(3) Understanding the principles of asepsis, sterilization, sterile and non-sterile supply storage, and integrated materiel management. Must recognize potential infection problems and be aware of possible cross-infection problems as they relate to handling, sorting, delivering, and storing supplies.

(4) Participating on a variety of medical center committees including:

(a) Infection Control Committee.

(b) Resuscitation/CPR Committee.

(c) Commodity Standards Committee.

(5) Function as a fund control point official; plan and develop annual budget.

(6) Develop and implement a continuing program for education and staff development. The Chief, SPD, shall be responsible for the establishment of an initial orientation and recurring on-the-job training program for new and established SPD employees.

(7) Provide continuous technical and administrative supervision of personnel. Carrying out a constructive counseling program and initiating recommendations for action involving SPD employees.

(8) Interview applicants and make recommendations for selection and placement within the SPD section. This includes regularly updating job descriptions and performance standards for SPD personnel.

c. Supervisors/team leaders are responsible to the Chief, SPD. Their activities include training new employees, conducting regular in-service training, preparing work assignments, and maintaining stores.

d. Medical supply technicians and supply clerks are responsible to the supervisors. In general, their duties include, but are not limited to, the daily processing/preparation of needed supplies and equipment, and inventory/replenishment of supplies to consumer units. Employees engaged in these activities must be extremely conscious of details.

4. 104 COMMODITY STANDARDS

a. The Commodity Standards Committee is designed to improve the quality, effectiveness, and efficiency of supply support furnished to using services and to assure availability of supplies and equipment at a cost consistent with the quality required.

b. It is recommended that the Commodity Standards Committee Membership include the following:

(1) Chief, SPD (Chair or Co-Chair)

(2) Infection Control Representative

(c) Pharmacy Representative

(d) Bio-Medical Representative

(e) Surgery Representative

(f) Medicine Representative

(g) Patient Care/Nursing Representative

(h) Chief of Staff Representative

(i) Pathology/Laboratory Representative

(j) Fiscal Representative

(k) Environmental Management Representative

(l) Risk/Quality Management Representative

c. The objectives of the Commodity Standards Committee are as follows:

(1) Reduce the number of sizes, kinds, types, and grades of items to those essential to meet VA program requirements.

(2) Assure economical purchasing and distribution.

(3) Ensure all essential requirements of affected services are accommodated by obtaining concurrence of the using department or service head prior to standardization of the item.

5. 105 HOURS OF OPERATION/AFTER HOURS ACQUISITION

a. The hours of operation for the SPD section are based on several variables, some of which are not under the control of the Chief, SPD. The exact operating hours depend on the following:

(1) Staffing (FTE).

(2) Complexity of the operation.

(3) Amount of service provided.

(4) Requirements of the medical center and/or clinics.

b. The goal of each SPD section is to be a total support operation that provides coverage for as many hours as the resources will allow. The stock level of routinely used items will be kept at a level which will make this support possible and meet the needs of the customer.

c. The Chief, SPD, will compile and post a "locator list" of all items stocked by SPD. All SPD and nursing staff members shall have easy continuous access to this list. This locator list should have the items listed alphabetically by brand, common, and slang names.

d. If SPD is not staffed 24 hours a day, 7 days a week, a key will be provided for nursing or other staff members who will need access to the department. Detailed after-hours procedures will be posted (log sheet), instructing people how to sign out equipment and supplies. The log sheet will be monitored daily to evaluate ways SPD can improve services provided and will include the following:

(1) Item description

(2) Item destination

(3) Personnel obtaining item

(4) Time and date the item was removed from SPD

(5) AEMS/MERS ID Number, Preventative Maintenance Number, or Serial Number

NOTE: The following information will be posted in Section 1, Part 1, of the "SPD Desk Guide." (The SPD Desk Guide is the hardback binder used to file all SPD-related directives, handbooks, manuals, and operating instructions. The desk guide will be maintained in the office area of the Chief, SPD. The contents of the desk guide will be made available to all personnel responsible for performing SPD duties for the facility.)

1. Hours of operation

2. Personnel authorized access after hours:

a. List of the personnel authorized and the procedures they are to follow while accessing the area

b. Copy of the Log Sheet

PART 2. EMPLOYEE DEVELOPMENT

1. 201 ORIENTATION PROGRAM

a. The Chief, SPD, will be responsible for establishing an initial orientation and continuing an on-the-job training program for new and established SPD employees. This will include the SPD Level I training and completion of all text and workbook assignments (over a 20-week time frame) from the SPD training manual. Emphasis will also be placed on the following:

(1) Sterilizer and processing equipment operation

(2) Hazardous chemical and Material Safety Data Sheets (MSDS) requirements for SPD

(3) Storage/distribution of sterile supplies

(4) Microbiology and infection control procedures

(5) SPD operational requirements

b. During the initial orientation, a new SPD employee must complete the SPD Level I training program. All participants are required to take the end-of-chapter test. They must receive a passing score of 80 percent on each test. Participants scoring below 80 percent will be allowed to review the chapter and take the test as many times as necessary for satisfactory completion. When the entire series of chapters and tests have been completed successfully, participants will receive a Certificate of Completion signed by the Chief, SPD, or designee. Upon completion of the text and workbook assignments, SPD employees may request to take the certification examination (Level II) established by Central Office. The request must be made no later that 90 days after completing the Level I training. The certification examination will consist of a wide variety of questions and will be scored by Central Office. Participants who obtain a passing grade (85 percent or better) will receive a document of certification signed by the Deputy Assistant Secretary for Acquisition and Materiel Management. Certification can be maintained current only by the accumulation of Continuing Education Units (CEUs). Annual CEU requirements will be issued with the certification document. Central Office SPD program officials will monitor CEU completions submitted by the Chief, SPD, for all employees.

c. Orientation Training Prior to Operation of Equipment (Ethylene Oxide Sterilizers). After initial assignment within SPD, but prior to the operation of ethylene oxide (EtO) sterilizers or aerators, complete orientation and hands-on training must be provided for all SPD employees. This training must include:

(1) EtO sterilizer, aerator operation and maintenance.

(2) Work practices/precautions for safe use of EtO.

(3) Safe handling and storage of EtO tanks.

(4) Physical and health hazards of EtO.

(5) Accidental spill/leak plan.

(6) Emergency first-aid procedures.

(7) Personal protective equipment.

(8) Personnel EtO monitoring methods and the right to observe monitoring (29 CFR 1910.1047 (L).

(9) Requirements listed in 29 CFR 1910.1047 (j)(3).

d. All employees who work in an area of potential exposure to EtO will be provided with information and training on EtO at the time of initial assignment to SPD and at least annually thereafter. Employees will be informed of the following:

(1) The requirements of the Department of Labor, Occupational Safety and Health Administration (OSHA), 29 CFR Part 1910.1047, Occupational Exposure to EtO Final Standard, with an explanation of the contents.

(2) Any operations in the work area where EtO is present.

(3) The location and availability of the written current OSHA rule.

(4) The medical surveillance program required by the EtO final rule, with an explanation of appendix C of 29 CFR part 1910 (refer to part 3 of this handbook 29 CFR, part 1910).

e. The medical facility must ensure that no employee is exposed to an airborne concentration of EtO in excess of one part of EtO per million parts of air (1 ppm) as an 8-hour time weighted average (TWA). A schedule of employee rotation will not be used as a means of compliance with the TWA.

f. The Chief, SPD, will review the required EtO baseline survey report as conducted by a qualified industrial hygienist. The Chief, SPD, will coordinate with the responsible service chief and the facility safety and fire protection engineer to ensure employee safety and compliance with the OSHA EtO standard.

2. 202. Continuing Education. The Chief, SPD, will be responsible for the establishment of a continuing education program. All employees will participate in the continuing education program. In-service education meetings focusing on the technical aspects of SPD are held at least once a month. Although the primary focus of the training will be on the technical aspects of SPD, emphasis will also be placed on:

(1) Supply Management Concepts.

(2) Safety.

(3) Personnel Management.

(4) Quality Assurance/Risk Management.

(5) Anatomy and Physiology.

(6) Terminology.

(7) Inventory Management.

(8) Communication.

(9) Infection Control.

d. A training folder will be maintained for each employee documenting course of instruction and date of attendance. A file will also be maintained outlining the training schedule and course curriculum. Participation in this training program will be considered, along with other relevant factors, in SPD promotion actions.

e. Job certification is retained by the accumulation of CEUs annually.

(1) CEUs may be obtained in, but are not limited to, the following ways:

(a) Membership in National Organization (Membership for the Chief, SPD, is provided by Headquarters)	3.0
(b) Membership in Local Organization	2.0
(c) Attendance of Local Central Service (CS) Meeting	1.0*
(d) Attendance of Professional (SPD)CS/Logistics/Materiel Management Seminar, Related to SPD functions or operations (1.0* CEU per education day)	1.0*
(e) Publication of an SPD-Related Article (Professional or Station Publication)	4.0
(f) Orientation/Training Presentation Outside Service	1.0*
(g) Accredited College Courses	1.0*
(h) Public Relations Career Day/Health Fair (Presenter)	3.0
(i) Public Relation/Career Day/Health Fair (Attendee)	1.0
(j) Inter/Intra-Departmental In-Service (Presenter)	3.0
(k) Inter/Intra-Departmental In-Service (Attendee)	1.0*

(2) The requirements are as follows:

(a) Chief, SPD, must obtain 20 CEUs annually.

(b) SPD supervisory personnel must obtain 17 CEUs annually.

(c) SPD technicians must obtain 15 CEUs annually.

***CEU Per Education Day**

3. 203 CAREER DEVELOPMENT. The Chief, SPD, will promote SPD staff career development. Staff members should be encouraged to obtain membership in professional associations and investigate off-station educational opportunities. Career development goals should be reviewed during the formal annual and mid-term performance reviews.

4. 204. TRAINING DOCUMENT. Written outlines of all employee training programs will be maintained on file in SPD and will be revised as necessary. All training will be documented.

PART 3. INFECTION CONTROL

1. 301 HEALTH/PERSONAL HYGIENE. Careful attention to personal hygiene and good health will minimize the potential for acquiring or transmitting diseases. All SPD employees must help ensure that medical supplies and equipment are decontaminated and processed under the best possible conditions for maximum safety and protection of patients, employees, and visitors. To that end, the following guidelines must be observed:

a. The use of tobacco products, eating, drinking, or the storage of food items (including beverages) will not be permitted in SPD where the processes of decontamination, sterilization, supply storage, data equipment handling, or dispatching of patient care supplies or equipment is performed.

b. Portable fans will not be used in any SPD area.

c. Traffic in SPD is restricted to authorized personnel. Other persons with official business, and when accompanied by an appropriate supervisor or designee, will be authorized entrance to SPD. Individuals seeking entrance will wear and dispose of suitable personal protective equipment as specifically defined under Work Attire in this part. Personnel performing equipment repair, building maintenance, and housekeeping activities will wear prescribed work attire while performing duties in areas of SPD where special attention to epidemiological precautions is required. All protective clothing will be removed and properly stored or disposed of, as appropriate, prior to leaving the area.

d. Any SPD employee who reports for duty feeling ill or knowing that he/she may have an infection will report the condition to the supervisor immediately. The Employee Health Service is limited to emergencies or minor ailments that interfere with employees' ability to perform their duties during working hours. The employee will be referred for treatment to Employee Health Service in accordance with facility policy. The Employee Health Physician will provide emergency care to relieve discomfort while permitting employees to remain on duty. Before sending an employee off duty, the Employee Health Physician will consult with the SPD Chief if he/she believes that the employee could be temporarily reassigned to another task or relieved from duty. Employees requiring extended or recurring treatment will be referred to their private physician for definitive care not related to Office of Workers' Compensation Programs (OWCP). If an illness is an "Occupational Illness or Disease," Human Resources will be notified and a "Federal Employee's Notice of Occupational Disease and Claim for Compensation" Form CA-2, will be completed. If an injury is in the "Occupational Injury" category, Human Resources will be notified. Form CA-1, "Federal Employee's Notice of Traumatic Injury and Claim for Continuation of Pay/Compensation," will be initiated along with VA Form 2162 (refer to Section 11, "Sample Forms" of the SPD Desk Guide for Forms CA-1, CA-2, and VA Form 2162).

e. Personal cleanliness is mandatory in SPD to prevent transmittal of infectious microorganisms to patients or coworkers. Special emphasis is placed on exposed skin, hair, and fingernails.

f. Wash hands frequently and thoroughly to prevent cross-contamination and the spread of nosocomial (hospital acquired) infections. All employees must wash their hands before going on duty, before and after meals, after using the bathroom, after handling soiled items, before entering clean areas to handle clean items, and before going off duty. Hand washing is the first line of defense against transmitting infections.

2. 302 RESTRICTIVE TECHNIQUES

a. Rented, borrowed, leased or trial equipment/reusable supplies/surgical instruments that are being brought into the medical center for use shall be processed through SPD decontamination. When situations like this occur between health care facilities and third parties, the reusable medical devices may be improperly cleaned, disinfected, or sterilized either before or after patient use. Improper handling of devices between uses can contaminate facilities and expose individuals, including health care providers and couriers who come into contact with this equipment, to infectious, bio-hazardous material. Also, the presence of residual organic material on such equipment may compromise the effectiveness of sterilization procedures. The health care facility must verify that manufacturer's instructions for cleaning, disinfecting, or sterilizing the device are followed. If the medical center is utilizing a third-party supplier for reprocessing or sterilizing medical devices between uses, medical center staff must ensure that the manufacturer's specification, and the medical center policies are fulfilled. Standard operating procedures will be developed by each SPD Chief to ensure that clean/sterile equipment/supplies are being provided for direct patient care programs. These medical devices may not have been properly cleaned, disinfected, and/or sterilized prior to delivery to the medical center.

b. Single-use disposable medical devices will not be re-sterilized and/or reused. Reusable devices should be purchased if the intent is to re-sterilize and reuse them. If a package containing an expensive sterile disposable devise is opened and the item is not used, the manufacturer should be contacted for either the possibility of exchange or credit. In the absence of either service provided by the manufacturer, the device will not be repacked or over-wrapped and re-sterilized.

c. Expired devices. The medical device expiration date pertains to the safe use of the product; that is, the device, or some component part of the device, may have reached a point beyond which it is safe to use due to time, light, or other factors. Simply re-sterilizing the product may not render the device safe for patient use. If a device has reached its expiration date, the original manufacturer should be contacted to obtain credit or exchange the device.

d. Random samples of sterile items procured commercially or processed in SPD will not be subjected to sterility testing except as requested by the Infection Control Committee for evaluation of specific problems.

e. Staples, paper clips, pins, tape (other than chemical indicator tape), and other similar items will not be used in conjunction with the packaging, sterilization, or storage of supplies as they may promote accidental contamination. Sterilized chemical indicator tape should only be used to hold a package together. Unsterilized chemical indicator tape will not be used to hold packages or items together. Chemical indicator tape used in such a manner could jeopardize

patient care in that it suggests that an item is safe for patient use when it is not. Rubber bands will not be used to band items together for sterilization, storage, or delivery. This applies to items processed in SPD as well as to sterile supplies from a commercial source.

Note: Medical devices that are used in the morgue or animal research will not be processed (decontaminated, cleaned, or sterilized) in SPD. The reason for this is that the universal/standard precautions do not meet the requirements for certain microorganisms and prions that are found in research and autopsies.

f. Temperature and humidity will be controlled in all areas of SPD. Temperature will be maintained between 65 and 72 degrees Fahrenheit. Humidity will be maintained between 35 and 75 percent.

3. 303 WORK ATTIRE/PROCEDURAL TECHNIQUES. SPD is the central processing center where patient care devices are rendered safe for use. It consists of separate and distinct work areas where environment control is essential to the appropriate processing of sterile supplies.

Attention to proper dress attire is a fundamental element of the SPD Quality Improvement/ Benchmarking Program. The areas of SPD and the required work attire for each area are described below.

4. 304 DECONTAMINATION AREA

a. This area is used for reducing the bioburden of reusable medical supplies, instruments, or equipment. Utilizing the universal/standard precaution concept that all items received are considered contaminated, specific attire is required to protect the employee's personal protective equipment. Special attire will consist of the following:

(1) Scrub suits (not considered PPE).

(2) Approved head and hair covering.

(3) Face shields (cover from ear lobe to ear lobe and below the chin). If a face shield is not utilized, safety glasses/goggles will be worn with a surgical face mask.

(4) Long cuffed rubber/vinyl decontamination gloves (not surgical gloves).

(5) Impervious gown (this should be either disposable or reusable; long sleeved; fluid-impervious from elbows to cuff and from neck to bottom of gown; and length will be below the knee).

(6) Impervious shoe covers (not paper shoe covers).

(7) Jewelry is limited to wedding rings and post earrings.

(8) False fingernails will not be permitted.

(Note: The above attire will not be stored in the decontamination room; it will be put on before entering the decontamination area and will be removed before leaving the decontamination area. No one is to be in decontamination without wearing the proper attire).

b. The decontamination attire for picking up contaminated items from soiled pick-up areas will consist of:

(1) Cover Gown - may be used to protect the scrub suit and must be removed after completion of pickup.

(2) Exam Gloves - will be changed after each pickup. Gloves should not be worn when transporting items back to the decontamination area. This prevents the contamination of elevator buttons, light switches, doorknobs, etc. Clean gloves for transporting items back to the decontamination area are not required and should not be a practice that technicians use. If the technician feels that the items being picked up are soiled, e.g., IV pump & poles, commode chairs), then the items should be covered and transported to the decontamination area.

c. Decontamination pick-up at Nurse Servers will be the same as the decontamination area, but PPE will be changed from one pick-up area to the next (ward to ward).

d. PPE worn while working in the decontamination area will not be worn in any other area of SPD or the medical center. All PPE will be removed prior to leaving the decontamination area. There must be an area outside of the decontamination area for changing decontamination work attire (scrubs). A freshly laundered set of clothing will be used each time an employee leaves this area. If this procedure is not appropriate, a cover gown must be worn. At the completion of the decontamination tour of duty, employees will shower if the facility layout permits.

5. 305 PREPARATION AREA. The preparation area is used for the assembly and final processing of sterile medical supplies, instruments, and equipment. Strict control of this environment is critical to attaining and maintaining a high degree of confidence in sterile item integrity. The preparation area attire will consist of:

a. Scrub suits with long sleeves. If short sleeved scrub suits are provided, then a warm-up jacket or gown with long sleeves must be worn to cover the arms. Attire worn in this area will not be worn in other areas of SPD or the medical center without a long sleeve cover coat.

b. Head, mustache, and beard coverings.

c. Footwear for use in SPD or the medical center facility is recommended and should be maintained in the employee's locker.

6. 306 DISTRIBUTION/STERILE STORAGE AREA. The distribution/sterile stores area of SPD is used for maintaining and disseminating supplies, instruments, and equipment throughout the medical center. The specific attire of choice for this area is the regular SPD uniform consisting of white pants and blue zipper-front smock. The case cart area of the clean/sterile storage area must be segregated and the dress attire will be long sleeve scrubs, head and beard covers.

7. 307 ADMINISTRATIVE AREA. If SPD has a separate office/clerical support area, staff in this area should wear clothing suitable to their duties and responsibility. Upon entering the other SPD areas, they will wear the appropriate cover gowns, warm-up jackets, etc.

8. 308 NURSE SERVERS. Nurse servers are self-contained storage units that are located at each patient care room. These units serve a dual purpose in that one is used to stock sterile/clean medical supplies and the other one is for soiled medical supplies. These servers have doors on both sides (one on the hallway and one inside the patient room). If nurse servers are utilized, clean and dirty supplies **must** never be mixed. These doors will remain locked at all times when not in use to prevent unauthorized individuals from having access to medical supplies and to prevent injury to patients from contents within. Medical supplies stocked in these servers should be standardized and reviewed periodically to reduce waste, contamination, and excess stock.

9. 309 PHYSICAL RESTRICTIONS. Physical separation of soiled from clean areas must be maintained to assist in the prevention of cross-contamination. Separation of clean from soiled also applies to patient care supplies and equipment in SPD and throughout the medical facility.

a. If the same individual must handle the supplies before and after decontamination, that person must complete the following actions prior to performing assignments in other areas:

(1) Remove the personal protective equipment (PPE) (e.g., cap, gown, and gloves).

(2) Change into appropriate clean attire.

(3) Wash and dry hands thoroughly (a shower is recommended).

b. To maintain and control a clean environment in SPD, there must be no exposed pipes, ducts, or cables to collect lint and dust. Light fixtures should be recessed.

10. 310 TRAFFIC CONTROL. Traffic in SPD is restricted to authorized personnel. Other persons with official business, and when accompanied by an appropriate supervisor or designee, will be authorized entrance to SPD. Non-SPD personnel will wear attire appropriate to the area to which they are visiting/working. Work attire will be removed and/or disposed of, as appropriate, prior to leaving the area.

a. People Flow (more commonly known as traffic control in SPD) is controlled to minimize contamination due to microorganisms found on human bodies and clothing. Only authorized personnel who are properly attired are allowed in SPD. Traffic patterns within the SPD area are designed so that the “people flow” is always directed from clean to contaminated areas.

b. Material Flow is generally considered to be either incoming contaminated items or clean/sterile supplies. Contaminated items enter the decontamination area in covered containers. Before leaving the decontamination area, all items are cleaned and disinfected. Clean or sterile packaged items coming into SPD will be removed from shipping cartons and corrugated boxes before entering sterile storage. Shipping cartons are considered contaminated and are not appropriate in the SPD clean/sterile storage areas. Corrugated boxes cannot be cleaned and, therefore, are not allowed in the distribution or clean/sterile storage area.

c. Work Flow is the order in which medical/surgical items are received into SPD, processed, and dispensed for patient use without cross-contamination occurring. Contaminated reusable items are transported to the decontamination area in such a manner as to protect people and the environment from contamination. After the decontamination process, items go to the preparation/sterilization area where they are inspected, packaged, and sterilized as necessary. They are then transferred to the sterile storage area and maintained until issued. Items that do not need to be sterilized for patient care use will go from the decontamination area to the dispatch area. "Work Flow" always goes from dirty to clean areas.

d. Air Flow is carefully controlled in SPD to minimize the movement of microorganisms from dirty areas to clean. This is controlled by creating a positive air flow in the clean areas of SPD. Positive air flow means that a greater amount of air is forced into a room than is exhausted. This forces the air to seek other routes of escape, i.e., through doors, service windows, and other cracks and crevices. Positive pressure makes it difficult for airborne particles to enter that space. The dirty areas of SPD are maintained under negative pressure. Negative pressure occurs when more air is exhausted from the room than is supplied, thus creating air flow into the dirty areas through doors and minimizing the escape of airborne microorganisms. The positive flow in the clean areas of SPD is exhausted through the dirty areas to the outside or a filtered recirculating system.

(1) Ten air exchanges per hour are required in the clean areas of SPD.

(2) Six air exchanges per hour are required in the decontamination area.

11. 311 UNIVERSAL/STANDARD PRECAUTIONS

a. The practice of Universal/Standard Precautions is to be followed by all healthcare workers whose functions could bring them into contact with blood, body fluids, or body substances. All of the precautions mandate that all contaminated items are treated as if they are known to be infectious. Precautions also include frequent hand washing and the use of PPE.

b. All employees will review Universal/Standard Precautions annually.

12. 312 CLEANING/SANITIZING SPD

a. SPD personnel are responsible for cleaning all work surfaces and sinks daily, using an approved disinfectant. Sterilizers are cleaned regularly according to the manufacturer's instructions. Sterilizer door gaskets, chamber drain screens, and external surfaces are cleaned daily using a lint free cloth and clean water. The internal chamber will be cleaned weekly. Other areas such as storage shelves, breakout rooms, training area, ward closets, and equipment storage areas are cleaned weekly, or more often as necessary.

b. In cooperation with Environmental Management Service, a written daily cleaning schedule for SPD areas will be developed, implemented, and enforced. Cleaning encompasses wet mopping or wet vacuuming of floors with a suitable germicide at least once a day and more often if necessary. Walls, ceilings, vents, and filters should be cleaned at least monthly. Sweeping or dry dusting is prohibited in SPD.

c. Engineering Service is responsible for maintaining the ventilation system and inspecting filters at least quarterly. SPD will notify Engineering Service if interval changes are necessary.

13. 313 PEST CONTROL. SPD areas must be kept free of insects, rodents, and other vermin. The Chief, SPD, will develop a routine schedule for spraying SPD for pest control. Reports of pest infestations will be investigated, and appropriate action must be taken.

PART 4. INVENTORY MANAGEMENT

1. 401 COST CONTROL PROCEDURES/REPORTS. SPD will prepare and maintain an annual budget. All procurement actions will be in accordance with the relevant procurement laws and regulations, and specifically those found in the Federal Acquisition Regulation (FAR), Veterans Affairs Acquisition Regulation (VAAR), and section 8125 of title 38, United States Code, "Procurement of health-care items." Additionally, SPD will strive to have in stock all items needed for the healthcare provider in treating the patient. SPD will maintain an average turnover rate of 12 turns per year or in accordance with VHA policy and performance measure requirements. This applies to all stock items (posted and unposted). Items that do not meet this turnover rate will be listed and reviewed every 6 months for their continued need to be stocked. SPD will prepare and maintain a cost analysis for each individual customer/user. This is accomplished by utilizing the Cost Distribution Report found in IFCAP (Integrated Fund Distribution, Control Point Activity, Accounting and Procurement/Generic Inventory Package (IFCAP/GIP). Upon total implementation of the GIP in IFCAP, this will be accomplished by utilizing the "History Distribution Report" for cost analysis and the "Usage Demand Analysis Report" to ascertain appropriate stock inventory levels.

2. 402 PROCUREMENT PROCEDURES. Utilizing the IFCAP system, all supplies will be ordered in a manner that will ensure their availability when needed and to keep the total dollar investment in inventory as low as possible. When selecting and ordering supplies, guidance for the process can be accessed in section 8125, title 38, United States Code, which dictates mandatory sources and cost savings. All medical supplies for the medical center should be standardized as much as possible. All items that are not on contract should be reviewed to make sure no substitute contract item is available. If an item or its substitute cannot be found either from a mandatory source or on contract, that item should be submitted as a candidate for a possible consolidation contract. The goal of SPD is to maintain a minimum stock level while still meeting the needs of the medical center. Stock levels should be as follows or in accordance with VHA policy and performance measure requirements:

a. For posted stock items (warehouse stock items) SPD should have a 7-day level on hand.

b. A 14-day level should be on hand for unposted items.

3. 403 SOURCE CODES. Source codes are assigned to different items procured by the Government as required by the Federal Property Management Regulations, 41 CFR, chapter 101, part 101-26, "Procurement Sources and Programs." The following VA-assigned source codes are in IFCAP (after consideration has been given to the use of VA excess property):

a. 2 - Local Procurement (Open Market) – **This source code should be used to obtain an item only if that item is not available from any other source**. An open market source is a non-Government, non-contract commercial source such as a medical/surgical company, which does not have a contract for this item. Therefore, it is important to purchase supplies from mandatory sources whenever possible, not only to hold down costs, but to stay within the law.

b. 4 - VA Decentralized Schedules (VA Contracts)

c. 5 - Federal Prison Industries

d. 6 - Federal Supply Schedules (FSS Contracts and Disadvantaged)

e. 7 - Consolidated Procurement

f. 9 - National Acquisition Center Contracts

g. A - Excess from Other Facilities

h. B - Combination of Sources 2, 4, and 6 (Prime Vendor)

4. 404 RESERVED.

5. 405 PURCHASING NEW ITEMS. Requests for purchase of new or substitute products will be directed to the Commodity Standards Committee Chairperson, who will review the product and justification for purchase. The Chief, SPD, or designee will initiate evaluation action prior to committee review. The Commodities Standardization Committee will review all requests for the purchase of any new expendable medical supplies prior to purchase action being taken. The feasibility of any new product relative to increased cost and improved patient care will be evaluated and compared to similar items, which may be available. If additional cost is involved, a purchase action for additional recurring funding cannot be initiated prior to approval by the Resources Committee. Emergency purchasing will not be delayed by the committee, but will be handled promptly. The Chief, SPD, will maintain a record of such emergency purchases, and these records will be included in the minutes of the next committee meeting.

6. 406 CUSTOMER IDENTIFICATION. Supplies in the medical center should be centrally managed to provide total supply support to all areas of the medical center and clinics as outlined in the VA Program to Guide the Reinvention of Enhanced Supply Support (PROGRESS).

PART 5. SAFETY STANDARDS

1. 500 AUTHORITY

a. VA Directive 7700 and VA Handbook 7700.1, both titled “Occupational Safety and Health”

b. 29 CFR 1960, “Basis Program Elements for Federal Employee Matters”

2. 501 FIRE. All SPD employees will review the medical center fire plan upon initial employment and annually thereafter. Actions to be taken during a fire shall involve all personnel in the area of the fire or drill. Specific procedures to be followed by SPD personnel in case of fire or drill in SPD can be found in section 6 of the SPD Desk Guide.

3. 502 DISASTER. During an internal or external disaster, SPD is responsible for providing materials for emergency use. SPD will coordinate the issue and delivery and receipt of supplies and equipment in accordance with the medical center’s disaster plan (refer to the SPD Desk Guide for the Disaster Plan). All SPD employees are required to review the medical center’s disaster plan upon initial employment and annually thereafter.

4. 503 INJURY REPORTING

a. All injuries sustained by employees while on duty shall be reported to the Chief, SPD, immediately. The employee will be sent to the Employee Health Physician or the Medical Officer on Duty for initial treatment and documentation of the accident. Human Resources will be notified of the injury and, within 72 hours, a Federal Employee’s Notice of Traumatic Injury and Claim of Pay/Compensation, Form CA-1 will be filled out, in part by the employee, if possible.

b. The supervisor is responsible for assisting the employee in the completion of Form CA-1, including obtaining statements from any witnesses and routing the form to Human Resources as soon as possible. The supervisor is also responsible for filling out VA Form 2162 for routing to the medical center safety officer.

5. 504 ETHYLENE OXIDE (EtO). All new employees who work in or frequent an area of potential exposure to EtO will be provided with information on EtO at the time of initial duty in SPD and at least annually thereafter. The orientation course will include:

a. Policies and procedures for prevention maintenance of EtO sterilization and aeration equipment. Engineering Service has an established preventative maintenance program, which documents the date and circumstances of each leak detection survey and of other maintenance procedures.

b. Work Practices/Precautions for Safe Use of EtO

(1) Monitoring. Monitoring will be conducted to ensure that the employee is not exposed to an airborne concentration of EtO greater than one part per million parts of air (1 ppm) on an 8-hour, time-weighted average (8-hour TWA). The supervisor will ensure that this monitoring is completed using approved monitoring devices such as badges or filters. The employee shall also be assured that they are not exposed to an airborne concentration of EtO in excess of five parts per million Short Term Exposure Level (STEL) of EtO per million parts of air (5 ppm) as averaged over a sampling period of 15 minutes. A determination of employees' exposure shall be made from breathing zone air samples that are representative of the 8-hour TWA and 15-minute short-term exposure of each employee.

(2) Monitoring Frequency. If the initial monitoring reveals employee exposure at or above the action level but at or below the 8-hour TWA, repeat such monitoring for each such employee at least every 6 months. If the initial monitoring reveals employee exposure above the 8-hour TWA, the exposure problem must be remedied and the exposure levels reduced below the 8-hour TWA. Furthermore, such monitoring for each such employee must be repeated at least every 3 months.

(3) Additional Monitoring. Additional monitoring is required as follows:

(a) When a change has occurred in the production process, control equipment, personnel, or work practices that may result in new or additional exposures to EtO.

(b) When there is any reason to suspect that a change may result in new or additional exposures to EtO.

(c) When there is any reason to suspect that a change may result in new or additional exposure.

(4) Ventilation alarms are required to indicate whether or not the dedicated exhaust system is working properly.

(5) Respirators. Respirators that have been approved as being acceptable for protection against EtO by the Mine Safety and Health Administration (MSHA) and by the National Institute for Occupational Safety and Health (NIOSH) under the provisions of 30 CFR, Part II, will be provided and readily available for use during any emergencies or when exposure to EtO is above the TWA or STEL. Supervisors will be fitted, trained, and approved for wearing respirators by the medical center Safety Officer or designee. The facility will have a written respiratory protection program in place and perform medical evaluations for employees as required by OSHA 29 CFR 1910.134.

(6) Medical Surveillance. A medical surveillance program must be in place and available to all employees who are or may be exposed to EtO (without regard to the use of respirators) for at least 30 days a year. The medical surveillance will include medical examination and consultations. The medical examination will be made available to the employee on the following schedule:

(a) Prior to assignment to SPD and areas or duties where potential exposure may occur.

(b) At least annually.

(c) At termination of employment.

(d) As medically appropriate for any exposure.

(e) At the employee's request.

(f) As soon as possible after suspected exposure to EtO.

(7) The medical examination will include:

(a) A medical and work history with special emphasis directed to symptoms related to the pulmonary, hematological, neurological, reproductive, integumentary (skin), and ophthalmology systems.

(b) A complete blood count to include at least a white cell count (including differential cell count), red cell count, hematocrit, and hemoglobin.

(c) Any laboratory or other tests which the examining physician deems necessary by sound medical practice.

(d) The content of the medical examination or consultation shall be determined by the examining physician, and shall include pregnancy testing or laboratory evaluation of fertility if requested by the employee and deemed appropriate by the physician.

(e) The employee will be provided a copy of the physician's written opinion of all medical exams and consultations.

NOTE: A complete text of OSHA Standards, part 1910.1047, can be found in section 3 of the SPD Desk Guide.

(8) Safe Handling and Storage of EtO Tanks

(a) Mixture EtO Cylinder Storage Restrictions. Cylinders of EtO gas mixture are stored in a temperature-regulated designated area that meets building codes and OSHA regulations. Tanks are stored and used in an upright position and are securely fastened in place by suitable straps or chains.

(b) Mixture EtO Cylinder Transportation. Cylinders of EtO gas mixture are transported to and from SPD on cylinder carts with chains securing them during transit. All EtO cylinders are stored in an area away from the flow of traffic. Cylinders that have been used and removed from service are handled in the same manner as full cylinders.

(c) 100 percent EtO Cartridges. If each cartridge contains 50 or more grams of EtO, only 1 day's supply of cartridges, up to a maximum of 12 cartridges, is stored in the immediate area of the sterilizers. If more than 48 cartridges are stored in the inventory area, then the storage area must conform to the recommendation of the National Fire Protection Association (NFPA).

(d) Disposal of 100 percent EtO Cartridges. Empty containers are placed along with regular non-incinerated waste. Containers containing EtO will be returned or disposed of in accordance with the manufacturer's instructions. If such containers are not returned to the manufacturer, disposal of the containers will be done in compliance with EtO health and safety requirements and applicable local regulations.

(9) Accidental Spill/Leak Plan. A written emergency action plan, which outlines procedures to follow in case of an EtO leak or spill, is posted adjacent to the EtO sterilizers and in the training room of SPD. The plan includes procedures for alerting personnel, avoiding EtO contact, evacuating and accounting for unprotected personnel, and re-entering SPD after the spill or leak.

(10) Area Monitoring of EtO. Although not required by OSHA, many VA facilities have installed systems to detect concentrations of EtO in the air. This is most often accomplished periodically by utilizing personnel monitoring badges. If an area monitoring system is used, the best method of EtO detection is by gas chromatography that is EtO specific. Many area monitoring systems are available which are not EtO specific, but will alarm merely with the presence of hydrocarbons that can be found in many cleaning solvents and alcohol. In order to prevent many false alarms in SPD and guarantee the proper response by employees in emergent situations, an EtO-specific monitoring system is necessary. The purpose of these systems is to detect high EtO levels in the work area before employees are exposed to them. Therefore, the alarm levels should be set at or below the exposure levels set by OSHA. Most systems have both a low and a high alarm. The low alarm in the work areas should be set at the action level of .5 ppm so the SPD Chief knows that action should be taken to determine the cause. The high alarm in these areas should be set at the TWA of 1 ppm. In the tank room and equipment maintenance access areas, the STEL is 5 ppm, so the alarm should be set only at this level to notify anyone working there to evacuate immediately. Placement of the sensing ports for the monitoring system is important. It is recommended that a monitoring point be located in any area of SPD that has a potential for EtO to leak into. In most SPD areas, if there is access to the EtO sterilizer, sample points should be located in the EtO tank room, equipment maintenance area directly in front of the EtO sterilizer at the work stations, in the preparation room, and directly in front of the sterilizer in the decontamination room (see part 5, paragraph 4. 504b. (1) of this handbook.)

(11) Emergency First-Aid Procedures

(a) Eye Exposure. If EtO gets into the eyes, flush eyes immediately with large amounts of water, lifting the lower and upper eyelids, using an OSHA-approved eye washer. Get medical attention immediately. Contact lenses should not be worn when working with this chemical.

(b) Skin Exposure. If EtO gets on the skin, immediately wash the contaminated skin with water. If EtO soaks through clothing, especially your shoes, remove the clothing immediately and wash the skin with water using an emergency deluge shower. Get medical attention immediately. Thoroughly wash contaminated clothing before reusing. Contaminated leather shoes or other leather articles must be discarded, not reused.

(c) Inhalation. If large amounts of EtO are inhaled, the exposed person must be moved to fresh air at once. If breathing has stopped, perform cardiopulmonary resuscitation. Keep the affected person warm and at rest. Get medical attention immediately.

(d) Swallowed. When EtO has been swallowed, give the person large quantities of water immediately. After the water has been swallowed, try to get them to vomit by having them touch the back of their throat with their finger.

NOTE: DO NOT MAKE AN UNCONSCIOUS PERSON VOMIT. GET MEDICAL ATTENTION IMMEDIATELY.

(e) Rescue. Any personnel that attempt rescue must wear an approved respirator for moving the affected person from the hazardous exposure area. If the exposed person has been overcome, attempt rescue only after notifying at least one person of the emergency and putting into effect established emergency procedures. ***DO NOT BECOME A CASUALTY YOURSELF.*** Understand your emergency rescue procedures and know the location of the emergency equipment before the need arises.

(12) Personnel EtO Monitoring Methods. Personnel monitoring is performed to determine the concentration of airborne contaminants in the breathing zone of employees. This measured concentration is assumed to be the level actually inhaled by personnel. Four EtO personnel monitoring methods are known to be in current use. The two most popular methods are charcoal tubes and passive sampling devices. Two other systems that have been used to a lesser degree are non-permeable bags and impingers.

(13) Hazard Communication. All SPD employees will review and familiarize themselves with the medical center Safety, Occupational Health and Fire Protection Program, upon initial employment and annually thereafter. The Chief, SPD, is responsible for providing employees with necessary information about all chemical products which are hazardous and to which they may be exposed.

(14) The Material Safety Data Sheet (MSDS)

(a) The MSDS is a printed or written document providing information on the physical and health characteristics of a hazardous material, as well as other information such as the chemical name, common name, trade name, manufacturer, and list of ingredients. Supervisors will ensure that all hazardous chemicals are properly labeled. Labels should list at least the chemical identity, appropriate hazard warnings, and the name and address of the manufacturer, importer, or other responsible party. Later information can be verified by referring to the corresponding MSDS. The MSDS for SPD will be accessible in designated work areas for all employees, such as Preparation Area, Dispatch, and Decontamination Area.

(b) Supervisors will ensure that all employees handling hazardous chemicals know how to interpret information on the label of chemical containers and information in the MSDS. MSDSs will be kept in hard copy format and indexed for easy access by employees. A list of MSDSs and where they are located can be found in section 10 of the SPD Desk Guide.

(15) Labeling/Handling/Storage of Hazardous Chemicals.

(a) Areas where hazardous materials are utilized and stored will be evaluated, and warning signs will be posted, where applicable.

(b) All SPD employees must be trained in the occupational hazards associated with hazardous materials, the practices and precautions required to work with the materials safely, and how to use an MSDS. Policies and procedures for hazard communication should be reviewed upon initial orientation and annually thereafter.

(16) Spills/Leaks/Exposure

(a) Spills or leak procedures for each hazardous material can be found in the MSDS (see part 6, paragraph 4.604, subparagraph d. of this handbook).

(b) Spills or leak procedures are accomplished in accordance with the medical center Safety, Occupational Health and Fire Protection Program (see part 7 of this handbook for Specific SPD Hazard Communication plan).

(c) Exposures to hazardous chemicals will be treated as outlined in the MSDS.

PART 6. DECONTAMINATION

1. 601 INTRODUCTION

a. One of the primary concerns of a medical facility is infection control. The medical center staff must follow all precautionary steps to minimize the spread of pathogens from one patient to another and to reduce bioburden. The supplies, instrumentation, and equipment used must be clean and sterile. Important aspects of infection control are the processes by which instruments and equipment are collected, processed, and handled.

b. Decontamination is the process of cleaning and disinfecting medical supplies and equipment. The SPD decontamination area of a medical center is where this process takes place. Personnel who work in this area are trained in the various methods of processing medical supplies and equipment for sterilization. The decontamination process plays a vital role in interrupting the transmission of infectious disease. **All reusable medical devices used in the medical center should be processed in the SPD decontamination area. If there are other areas of the medical center where decontamination must be done, all procedures listed in this section of the handbook will apply to that area.**

2. 602 DESCRIPTION OF DECONTAMINATION AREA

a. The decontamination area of SPD is a restricted area specifically designed to meet the medical center's needs for the reprocessing of supplies and equipment. This area will be physically separated. Supplies and equipment should be transported to the decontamination area in impervious bags, covered/closed carts, cart lifts, dumbwaiters, and automated transport systems. The area must have adequate lighting to allow for inspection of articles during processing. Ventilation must be under negative pressure allowing air to be pulled from areas outside of decontamination. Six air exchanges per hour are required in the decontamination area. Correct ventilation is essential to reduce cross-contamination into surrounding areas; thus, all windows and doors in this area must be kept closed.

b. The decontamination area is designed for and constructed with finished surfaces. These surfaces must withstand daily cleaning with a disinfectant to reduce the bioburden or microorganism count in the area. Personal protective equipment (PPE) is essential to an SPD technician's safety. Protective attire must be donned before entering the decontamination area. It is the technician's responsibility to understand the policies and procedures regarding protective attire in his/her work area or job assignment. Workflow should originate from outside the decontamination area and travel inside through a dedicated entry way and/or dumbwaiter/lift system. Articles are then processed and passed through to the clean side for further preparation and redistribution.

3. 603 PERSONAL PROTECTIVE EQUIPMENT (PPE)

a. Since the introduction of Universal/Standard Precautions, all used equipment and supplies are considered contaminated and must be treated as such. It is the medical center's responsibility to provide healthcare workers with PPE and training to promote personal safety. The medical center should also ensure that the employees wear the PPE. The types of PPE and restrictions used in SPD include:

(1) Scrub Suits (not considered PPE; however, they allow changing as necessary).

(2) Approved Head and Hair Covering.

(3) Face Shields (cover from ear lobe to ear lobe and below the chin). If a face shield is not utilized, safety glasses/goggles will be worn with a surgical face mask.

(4) Long Cuffed Rubber/Vinyl Decontamination Gloves (not surgical gloves)

(5) Impervious Gown (this should be either disposable or reusable; long sleeved; fluid-impervious from elbows to cuff and from neck to bottom of gown; and length will be below the knee).

(6) Impervious Shoe Covers (not paper shoe covers).

(7) Jewelry is limited to wedding rings and post earrings.

(8) False fingernails will not be permitted.

b. Personal protective equipment must be worn at all times in the decontamination area and must be removed whenever the technician leaves the area. After removing protective wear, the technicians must wash their hands. A fresh set of protective wear must be donned before reentering the decontamination room. Regular laundering and/or disinfecting of all reusable personal protective equipment is required to reduce cross-contamination. PPE will not be stored in the decontamination area. At the completion of the decontamination tour of duty, employees will shower if the facility layout permits.

4. 604 INFECTION CONTROL PRACTICES

a. Universal/Standard Precautions will be strictly followed in the decontamination area. It is the technician's responsibility to be familiar with, and adhere to, these policies and procedures for their own protection. Important areas include hand washing, sharps safety, spills, soiled laundry, infectious waste, and environmental cleaning.

b. Hand Washing (see part 3, paragraph 1.301, subparagraph f. of this handbook). In addition, hand washing is indicated in the following examples:

(1) Immediately after any contact with blood or body fluids.

(2) Immediately after gloves are removed.

(3) For personal hygiene, e.g., arrival at the work site, use of the lavatory, before and after eating, as well as before and after returning to the job site.

c. Sharps Safety. Sharps are defined as needles, scalpel blades, and other sharp objects that can penetrate the skin. Technnicians must not reach blindly into a container to retrieve items that cannot be visualized. Safe use must include:

(1) Inspect procedure trays for sharps.

(2) Always use a forceps to remove a scalpel blade from a reusable handle.

(3) Place disposable sharps in a puncture-resistant container.

(4) Never attempt to pick up broken glassware with your hands. Check procedures for proper disposal in your facility.

(5) Never put your hands in a sharps container.

d. Spills. Action must be taken to contain and clean up a spill immediately using the appropriate agent. When a disinfectant is used to clean an infectious material spill, the area must be allowed to air dry in order for the disinfectant to be effective. In the case where a large volume of potentially hazardous material has been spilled, the supervisor, safety officer, and Environmental Management Service will be contacted. Appropriate steps must be taken to reduce further exposure to industrial hazards.

e. Soiled Laundry. Soiled laundry will be placed in the appropriate laundry bag.

f. Infectious Waste. Items disposed of in decontamination will be discarded as infectious waste. Infectious waste is any item deemed to be potentially harmful to personnel or the environment by way of cross-contamination. Impervious containers must be provided in the decontamination area. The container must be emptied and disinfected regularly by environmental management.

g. Environmental Cleaning. In cooperation with Environmental Programs Service, a written daily cleaning schedule for SPD areas will be developed, implemented, and enforced. Cleaning encompasses wet mopping or wet vacuuming of floors with a suitable germicide at least once a day, and more often if necessary. Walls, ceilings, vents, and filters should be cleaned at least monthly. Sweeping or dry dusting is prohibited in SPD. Dedicated cleaning equipment will be provided for and maintained in the SPD decontamination area. This equipment will not be used in other areas of SPD or the facility. Personnel will never go from the decontamination area to the preparation area while cleaning.

5. 605 SAFETY

a. Eye Wash Stations. These are used for emergency eye flush in the case of a chemical splash in the eye. Technicians must be knowledgeable in how and when to use this equipment.

b. Physical Hazards. SPD staff must follow all safety procedures in the performance of their job duties. Proper body mechanics will always be used. All injuries, unsafe conditions, or practices will be reported immediately to supervisory personnel. Potential safety hazards in the decontamination area include, but are not limited to:

(1) Open Drawers.

(2) Sharps and Needle Sticks.

(3) Carelessly Stacked Washer/Sterilizer Baskets.

(4) Automatic Cart Washer Doors.

(5) Lifting Heavy Objects.

(6) Slick/Wet Floors.

(7) Automatic Loaders/Unloaders and Doors of Washer Sterilizers.

(8) Hot Items.

(9) Improper Use of Chemicals.

(10) Operating Equipment Noise.

6. 606 SOILED SUPPLY COLLECTION PROCEDURES

a. One of SPD's primary functions is the collection of contaminated supplies and equipment. All contaminated supplies and equipment will be collected in covered conveyances or containers, such as waterproof plastic bags, tote-boxes with lids, or closed or covered carts. Collection containers for holding soiled reusable supplies should be made of material that can be properly decontaminated or discarded. Care must also be taken to protect the environment when transporting contaminated items to SPD. All nursing units and clinic areas will have a dedicated soiled utility or "dirty" room. Enclosed carts or containers should be provided in these rooms, and all ward procedure trays and reusable equipment should be placed in them. These containers will be exchanged at each pick up location. Containers will be cleaned between each use. It is the user's responsibility to dispose of sharps appropriately and to remove or dispose of gross soil from items being returned to SPD.

b. The decontamination attire for picking up contaminated items from soiled pickup areas will consist of:

(1) Cover Gown - may be used to protect the uniform and must be removed after completion of pickup.

(2) Exam Gloves - will be changed after each pickup. Gloves should not be worn when transporting items back to the decontamination area. This prevents the contamination of elevator buttons, light switches, doorknobs, etc. Changing to clean gloves for transporting items back to the decontamination area is not required and should not be a practice that technicians use. If the technician feels that the items being picked up are soiled, e.g., IV pump & poles, commode chairs, then they should be covered and transported to the decontamination area.

(3) Decontamination pickup at nurse servers will be the same as the decontamination area, but protective clothing will be changed from one pickup area to the next (ward to ward).

c. Prior to transporting large equipment such as emergency carts, warming blankets, IV pumps, etc., gross soil will be removed at the point of use or the item must be placed in a closed container. In the absence of gross soil, these items may be transported as they normally would be throughout the medical center.

7. 607 SYSTEMS FOR COLLECTION AND TRANSPORT OF SOILED INSTRUMENTS AND SMALL EQUIPMENT

a. Solid Containers. Solid containers provide an excellent barrier to cross-contamination, as well as protection for the SPD technician. The container should be lightweight, durable, and made of material that can be properly decontaminated. The container should come with a lid that fits snugly over its opening.

b. Carts. Carts used for soiled collection and transport must be enclosed and dedicated for this purpose. Enclosed carts made of metal or plastic or open carts with solid bottoms and vinyl or plastic impervious coverings are acceptable. The cart should be easy to maneuver and decontaminate. Carts and coverings must be cleaned daily or more often if needed. Carts require regular maintenance; of particular importance are the wheels. Wheels must have routine lubrication to keep them moving freely and to avoid freeze up, which may occur due to repeated decontamination processing. Specialty carts will be cleaned between use, or as needed, and brought to the receiving area of SPD. Contents will be removed and inspected before taking the cart to the decontamination for processing. **Under no circumstances** will single use or disposal medical supplies be taken into the decontamination area unless they have meet the requirement for reprocessing as outlined in part 3, paragraph 302. b. of this handbook. Any item taken into the decontamination area must be considered contaminated. Any item that cannot be reprocessed (e.g., single use or disposable items) will be disposed of. Specialty carts will be taken to the receiving area and the cleaned items will be removed prior to the cart being taken to decontamination.

c. Automated Transport Systems. Types of systems available include monorails and robotics transport. The principle of operation for the two systems is similar. The robotics transport is the newer of the two systems. Components consist of an enclosed cart, guide track, programmable robot, and dedicated elevator(s). The technician can program the robot to retrieve a cart from a designated area. The robot travels to a designated area, automatically loads the waiting cart, and automatically returns it to the SPD decontamination area.

d. Dedicated Lifts/Dumbwaiters. These tools provide a system for delivery of contaminated supplies to SPD. They reduce handling and provide a direct link between the user area and SPD. They should be disinfected on a regular basis, and care must also be taken so that cross-contamination does not occur. Cart lifts and dumbwaiters must be dedicated as either clean or dirty and must not be interchangeable.

8. 608 DETERGENTS AND DISINFECTANTS

a. Detergents and disinfectants are the chemical agents used with manual and mechanical processing of instruments and equipment. Proper use of these agents helps reduce the number of microorganisms to a level that makes items safer to handle. All detergents and disinfectants must be prepared and utilized according to the manufacturer's instructions. Proper mixture is critical in ensuring that the detergent/disinfectant is effective, safe for use, and non-harmful to the medical device or environment that it comes in contact with. Technicians must be aware that mixing of chemicals can:

(1) Be harmful, even fatal, to themselves, others, and hazardous to the environment.

(2) Neutralize the effectiveness of the desired outcome.

(3) Cause corrosion or damage on contact.

b. Detergents.

(1) Detergents are used to aid in the removal of soil such as blood, pus, bone fragments, and urine from the surface of instruments or equipment. Soil gives the microorganism a place to live and colonize (grow in numbers). Instrumentation and equipment not properly cleaned will continue to afford sustenance to the contaminant and may impede the disinfecting and/or sterilization process.

(2) Detergents are utilized in both manual and mechanical processes of decontamination. They are normally chosen according to a pH level. A level of 7.0 is neutral. Any pH level below 7.0 is acidic. For example, vinegar and lemon juice are highly acidic. Acidic detergents can lead to rust and corrosion of instruments. Any pH level above 7.0 is alkaline. Most detergents and soaps are alkaline compounds.

(3) Detergents are used with:

(a) Ultrasonic Cleaner.

(b) Pasteurmatic Washer.

(c) Cart Washer.

(d) Washer/Sanitizer.

(e) Washer/Sterilize.

(f) Manual Processing/Pre-instrument Soak.

c. Disinfectants.

(1) Disinfectants are substances that destroy the growth of pathogenic microorganisms. However, they may have little or no effect on bacterial spores.

(2) Disinfectants can be classified according to their ability to kill microorganisms. In general, they may be classified into one of three levels: high, medium, and low. A high-level disinfectant will kill all bacteria, viruses, and fungi, but not bacterial spores. High-level disinfecting is appropriate for items that have come into contact with body tissue and fluids. High-level disinfecting is also an appropriate means of disinfecting items that come in contact with mucous membranes (respiratory devices, laryngoscope blades). High level disinfecting is not appropriate for devices that come in contact with broken skin or mucous membranes. If the object remains in contact with some high-level disinfectants long enough, bacterial spores can be killed. For example, soaking an instrument in gluteraldehyde for a minimum of 10 hours will kill bacterial spores. Some other examples of chemical disinfectants include chlorine dioxide, hydrogen peroxide, and peracetic acid-based formulation. Medium-level disinfectants kill most pathogenic microorganisms and some viruses. They do not kill bacterial spores. Medium-level disinfecting is appropriate for use on I.V. pumps, feeding pumps, etc. They are effective in killing such organisms as mycobacterium tuberculosis fungi, hepatitis B virus, and medium and small size viruses. Examples of solutions include chlorine compounds, alcohol (70 percent to 90 percent ethanol or isopropyl), and some phenolic and iodophor compounds. Low-level disinfectants kill some types of bacteria. They generally have little effect on viruses and do not kill spores. Low-level disinfectants are only appropriate for use in cleaning environmental surfaces, such as tabletops, floors, and walls. A disinfectant or detergent should always be used for what it was intended. If used properly, the solution will be able to perform effectively. SPD technicians must be familiar with the manufacturer's instructions for use of the chemicals.

9. 609 SOILED SUPPLY SORTING PROCEDURES. Every item that is returned to SPD decontamination requires cleaning/decontaminating as the first step in reprocessing. Items must be sorted as they are removed from the transport container according to the process or processes to be used. Items should be inspected for condition and missing parts and origins noted so that the user can be contacted to account for condition or to locate missing parts. Items are sorted into the following categories:

a. Equipment, Electrical.

b. Equipment, Non-electrical.

c. Rubber and/or Plastic Supplies.

d. Metalware.

e. Glassware.

f. Power Equipment.

g. Surgical Instruments.

h. Endoscopic Equipment.

i. Electronic Devices.

10. 610 CLEANING AND DISINFECTING PROCEDURES. The single most important procedure for good infection control and prevention of cross-contamination is the removal of all visible soil and proper application of a disinfectant. Follow specific equipment cleaning procedures provided by the manufacturer to assure the correct cleaning procedure (microbial harbors). Devices must be cleaned as soon after use as possible and as soon as they arrive in the decontamination area. The soaking of instrumentation is not recommended. In the rare instances that instrumentation should require soaking, only an approved soaking solution should be utilized. Detergents and disinfectants will cause damage and should **never** be used to soak instruments.

a. Equipment, Electrical. Manually wipe down equipment starting at the top and working down. Use a brush to reach all nooks and crannies. Handwash and inspect electrical cords, and coil, and secure with a binder. Wash casters and wheels last. Apply good aseptic technique when cleaning small equipment. Be sure to wipe the work surface (counter top) with disinfectant solution before turning the item over to be cleaned. Always rinse cloth in disinfectant solution prior to cleaning each used item of equipment. Examples of electrical equipment are infusion pumps, feeding pumps, K-pad motors, air compressor, portable suction machines, and hypothermia units.

b. Equipment, Non-electrical. Use the same procedure listed above to manually clean non-electrical equipment. If equipment can be mechanically cleaned, it should be inspected and pre-cleaned, removing all gross soil, tape, or residual adhesive before cleaning in a cart washer. Examples of non-electrical equipment are IV poles, wheelchairs, litters, K-pads, hypothermia blankets, seizure pads, foot cradles, commodes, and isolation carts.

c. Rubber and/or Plastic Supplies. Damage can easily occur to rubber and/or plastic supplies by using inappropriate chemicals or elevated temperatures. Manufacturers' instructions should be followed. Inspect each piece for tears, holes, or deterioration. These items can be cleaned or disinfected manually and/or mechanically. To manually wash items, use small brushes to clean inside tubes and rinse thoroughly. Items can then be dried by compressed air, tube drier, or air dried. When processing items mechanically in a washer/sterilizer, washer/sanitizer, or pasteurization machine, place items in the appropriate basket with insert before starting cycle. The baskets are needed to correctly position the items to facilitate washing and rinsing. Heavily soiled items may require pre-cleaning prior to mechanical processing. Supplies should be thoroughly dried before any further processing takes place. Examples of rubber and/or plastic supplies include nasal airways, oral airways, reusable ventilator tubing, reusable resuscitators, and pulmonary tubing.

d. Metalware. Inspect each item upon receipt for gross soil, and, if present, the item may need to be manually washed. Metalware can be processed through a cart washer, a washer/sterilizer, or a washer/sanitizer. It is important for the technician to use proper loading techniques. Appropriate baskets with inserts must be used to assure that the items are in the correct position during the processing cycle. In general, metalware with open depressions should be positioned open end down to facilitate drainage. Basket inserts also keep items from excessive movement in the chamber, which can cause damage to the items, chamber, or spray arms. If an item, such as a basin or instrument container, turns right side up and fills with water, the technician should be careful when handling -- burns may occur, protective gloves may be needed. Examples of metalware are bedpans, basins, medicine cups, and instrument containers.

e. Glassware. Care must be taken when handling glassware. Broken glass can cause a serious wound to staff or patient. These items can be cleaned or disinfected mechanically. The technician should first inspect each item for cracks and chips. Disassemble component parts. To pre-clean items, use appropriate brush and detergent. Scrubbing must be done under the surface of the solution. Items can then be processed through a washer/sterilizer or washer/sanitizer using appropriate baskets. Following the machine cycle, the items must be inspected for damage. A glass container may right itself during the cycle and fill with water. The technician must be careful when handling the container to avoid getting burned. Examples of glassware are syringes, medicine cups, evacuator, straight and Y connectors, and graduates.

f. Power Equipment. All power equipment must be inspected prior to processing. Manufacturers' recommendations will be followed regarding disassembly and cleaning. Examples of power equipment are:

(1) Battery Powered Equipment. Power source should be removed.

(2) Electrically Powered Equipment. Inspect electrical cords for cracking or fraying.

(3) Compressed Air/Nitrogen Powered Equipment. Remove the hose and inspect it for damage.

g. Surgical Instruments

(1) There is a wide variety of instrumentation available ranging in complexity and quality. SPD technicians must be familiar with the various instrument types and their special needs. Instruments, as well as all patient care equipment, are costly investments; proper handling will extend the useful life of the investment. Each instrument will be individually evaluated so that the most effective, economical, and appropriate cleaning and disinfecting method is selected. The types of instruments that will pass through SPD's decontamination area depend on the services offered at a medical center or clinic.

(2) Once in the decontamination area, inspect the instruments for tissue or bone remaining in the teeth or grooves. Remove this debris by holding the instrument under the surface of the solution and scrub the area with an instrument brush.

(3) During the initial cleaning and throughout the subsequent steps, instruments should be handled in such a manner as to avoid damage to the instrument and to prevent injury to the technician. Reprocessable sharps that have been used must not be processed in a manner that requires employees to reach by hand into the containers where these sharps have been placed. Instruments should be handled in small groups to avoid tangling and damage. Needles should be separated and processed separately. The technician should watch for scalpel blades still attached to knife handles (these should be removed and disposed of in sharps containers). All scalpel blades, disposable needles, saw blades, and drill points used during a surgical procedure should be disposed of by the operating room staff, but may be inadvertently overlooked. Many instruments contain sharp edges and parts, and the technician should take extreme care while handling any sharp item.

(4) During the cleaning process, always remember to open all instruments. For example, scissors must be opened, instruments with box locks cannot be left in a locked position, and multi-piece retractors, staplers, etc., must be disassembled prior to cleaning. This allows for all areas to be exposed to the cleaning process. The only exception to this rule is traumatic towel clips. Traumatic towel clips must be kept closed due to their sharpness.

(5) Items that can be cleaned by mechanical (sonic) methods will be placed into the ultrasonic cleaner. Items which cannot be immersed, microsurgical instrumentation (unless placed into a container purchased specifically for these instruments), cannulated items and items with lumens, will be cleaned by hand. Attention to all cannulated items, or items with lumens such as suction tubes, needles, and some orthopedic instruments, is vital. These areas may harbor blood and body tissue. Brushes are available from manufacturers in many sizes allowing access to the cannulated areas and will be used to assure any and all debris is removed.

(6) Ultrasonic Cleaner. The unit is designed to clean surgical instrumentation utilizing ultrasonic energy in a water-detergent solution. Understanding some of the technology involved with the operation of the ultrasonic cleaner is helpful. This unit converts sound waves into vibrations that remove residual soil from instruments. Microscopic bubbles are formed on the instruments and minute vacuum areas are created as the bubbles implode. This action draws out minute particles of debris from the instruments. The process is called cavitation. Rubber and plastic items should not be used in the ultrasonic due to their tendency to absorb sound waves and defeat the process. The cleaning solution used in the ultrasonic cleaner will be changed as needed; however, it is recommended that the water-detergent should be changed at least every 2 hours. Instruments should be placed loosely in the metal basket. Instruments should then be rinsed and processed through the washer/sterilizer. Items that cannot be processed through the washer/sterilizer should be rinsed and placed in the drying chamber of the ultrasonic cleaner. If a drying chamber is not included on existing equipment, the instruments should be air dried or patted dry with an absorbent material so that no water is left standing on the instruments.

(7) Microsurgical and delicate eye instruments should not be processed through a washer/sterilizer (unless placed in trays specially purchased for these instruments) because the turbulent action of steam mixed with water may damage them. Once these delicate instruments are processed through the ultrasonic cleaner, rinsed, and dried, they should be processed on a sterilize cycle only to assure a decreased bioburden is achieved to allow safe assembly by the preparation room instrument technician.

11. 611 MECHANICAL EQUIPMENT PROCESSING

a. There is a wide variety of processing equipment available for use in the decontamination area. The type of equipment used will depend on the items to be processed. Each piece of equipment is designed to process a selected group of instrumentation and/or equipment. The various types include:

(1) Washer/Sterilizer.

(2) Washer/Sanitizer.

(3) Washer/Decontaminate Utensil Washer.

(4) Ultrasonic Cleaner.

(5) Tube Washer.

(6) Pasteurizer.

(7) Scope Washer.

(8) Cart Washer.

(9) Hand Operated Steam Cleaning Device.

(10) Tube Dryer.

b. Washer/Sterilizer. This unit is designed to clean and sterilize. This is a gravity-type unit that can be programmed to wash or sterilize (steam under pressure), or a combination of the two. Generally the phases of the wash/sterilize cycle are wash, rinse, sterilize, and exhaust. Types of items that can be processed through a washer/sterilizer include: metalware, respiratory tubing, surgical instruments, and glassware. Only items specifically designed to be washed/sterilized should be put through the washer/sterilizer. Stainless steel instruments should not be processed close to instruments made of metals, such as nonanodized aluminum, brass, copper, or chrome plating. A reaction known as electrolysis may occur, resulting in one metal plating onto another. This reaction can result in permanent damage and staining. Ideally, demineralized or deionized water should be used in the washer/sterilizer to prevent mineral buildup and chemical reactions associated with regular tap water. A drying cycle should be set to assure the instruments dry completely and not emerge into the prep room wet after the cycle. Washer sterilizers will be biologically monitored at least weekly and mechanically monitored each cycle.

c. Washer/Sanitizer and Washer/Decontaminator. These units are designed only to wash and sanitize. For the sanitizing process, hot water or steam at atmospheric pressure is used to sanitize the load. Sanitization is less effective in killing microorganisms than a washer/sterilizer.

d. Utensil Washer. This unit is designed to clean metalware, instrumentation, and glassware. In general, the cycle includes a wash and a rinse. Depending on the type of machine, other options could include pre-rinse and special rinses, such as deionized or distilled water. Only items designed for this unit should be processed through it. The items should be inspected following washing to ensure that they are clean. Once items have completed this cycle, they must be processed through a sterilizer.

e. Pasteurmatic Washer. This unit is used to clean and disinfect plastic/rubber tubing and similar items. Pasteurization occurs using hot water at 170 degrees F (76.7 degrees C) for 30 minutes. This process is not effective against spore-forming bacteria.

f. Tube Dryer. This unit is used to dry plastic/rubber goods following cleaning and disinfecting. The unit draws in air and heats it. The hot air is then circulated into the cabinet. This facilitates drying the load. Following the cycle, the technician should check the items to ensure they are completely dry. Items that are not dried correctly may interfere with further thermal or EtO sterilization.

g. Endoscopic Equipment. There are two types of endoscopic equipment, rigid and flexible. The use of this type of equipment has increased, and the use is expected to expand. The popularity of endoscopes is due to the fact that they cause far less trauma to the patient. However, the equipment is very delicate and extremely expensive, and special attention must be given to the decontamination process. In regards to flexible scopes, there are two types: immersible and non-immersible. It is critical to make this determination before the cleaning process begins. Immersible scopes must be leak tested prior to taking any cleaning action before processing a scope. Always consult the manufacturer's instructions.

h. Rigid endoscopes are used primarily in the operating room but are also used in a clinical setting. Following use, the user wipes down the scope and places it in a covered container. The container is then transported to SPD's decontamination area. To manually process a rigid endoscope, first check the scope for damage, such as clouded lenses, bent instrument shaft, and burrs on the tip of the instrument shaft. Remove the fiber optic light cable from the scope. Wipe down scope, light cables, and adapters using an appropriate cleaning solution. Thoroughly rinse items by wiping them down with a water-dampened cloth. Careful attention should be paid to the lenses. Lenses should be wiped with an alcohol-dampened swab/applicator. The scope should then be dried thoroughly. Before processing any scope, the technician should consult all manufacturers' instructions. Examples of rigid scopes include arthroscopes, cystoscopes, bronchoscopes, and laryngoscopes.

i. Flexible endoscopes can be used by a variety of services within the medical center, such as G.I. Lab, Procto Clinic, Respiratory, Surgery, and ENT Clinic. Scopes should be wiped down and flushed with a cleaning solution immediately after use. The scope should then be placed in a covered container and transported to the SPD decontamination area. Since several different services use endoscopes, it is advisable to keep a check sheet in the decontamination area and record the location, serial number of each scope, date, and time in and out. Before processing any scope, the technician should consult all manufacturers' instructions. Flexible scopes can be cleaned and disinfected manually or through a scope washer. Examples of flexible endoscopes are sigmoidoscopes, colonoscopes, bronchoscopes, intubation scopes, and cystoscopes.

j. Manual processing of flexible endoscopes requires the following equipment: leakage tester, large basin of appropriate cleaning supplies, and brushes. To manually clean scopes, remove caps and/or valves on scope. Using an enzyme solution, brush the channel(s) and flush until completely clean. Hook up scopes to the leak tester (immersible scopes only) to check the integrity of the channel(s). This should be followed by an inspection of the outer casing of the scope. If no damage is detected, the scope is ready to be processed in a cleaning solution, followed by rinsing and drying. Scopes that are terminally sterilized by EtO, Steris, or those approved for plasma sterilization do not need and should not be processed in a cleaning solution such as gluteraldehyde.

k. Automated cleaning/disinfecting of flexible endoscopes requires the technician to have a thorough knowledge of how the scope washer operates. Before placing the scope in the scope washer, follow the steps outlined for manual cleaning. Once the manual cleaning is complete, the scope is ready to be processed in the scope washer. Follow the manufacturers' instructions for specific scopes and scope washers. Each different type of scope has a specific adapter. Selection of the correct adapter is critical. The adapters are fastened to the open channels of the scope so that there is access to the cleaning solution. Scopes that are terminally sterilized by EtO, Steris, or those approved for plasma sterilization do not need, and should not be, processed in a disinfecting solution such as gluteraldehyde.

l. Steris One. A sterilization method using paracetic acid that has been approved for endoscope processing. If the Steris One unit is used in SPD, it is recommended that the unit be placed in the decontamination area. This is due to the fact that the items are only clean, not disinfected, prior to placing them in the Steris unit. In addition, the items are wet when removed from the Steris sterilizer, which can lead to contamination of the prep unit if the Steris is to be located in the prep area. Steris does not have the benefit of packaging material and, thus, there is no way to maintain the sterility of the item from processing to the point of use. Scopes processed in Steris One must be passed through to the prep area, using clean gloves, immediately following the completion of the sterilization cycle. (Note. The Steris One is a sterilizer and must be monitored and records kept as any other sterilizer as outlined in part 8. 808 of this directive/handbook.

m. Electronic Devices. A variety of electrical cords, cables, and leads come to the decontamination area for processing. These items are delicate and should be handled carefully. The manufacturers' instructions should be thoroughly reviewed before processing this type item. General cleaning procedures are as follows:

(1) Inspect the outer case of the device for cracks, tears, or deterioration.

(2) Prepare a detergent solution, dampen cloth, and wipe down casing. Do not immerse the device in the detergent solution or use disinfectant unless the manufacturer's instructions indicate to do so.

(3) Following cleaning, the device should be wiped off with a water-dampened cloth. The device should air dry and then be sent to the preparation room. Examples of electronic devices are bovies, pacemaker cords, defibrillaltor paddles, EMG needles, EKG leads, and rectal probes.

n. Cart Washer. This unit is used to clean items such as carts, wheel chairs, litters/stretchers, and metal pan ware. In general, the cart washer cycle consists of a water/detergent phase followed by a water rinse. Cart washers can also be equipped with drying vents or a separate drying chamber.

o. Steam Cleaning Device. This is a hand held device (commonly called a steam gun) utilized for sanitizing items such as wheelchairs, litters, and carts. Steam cleaning devices can come equipped with detergent dispensers and water rinse options. Technicians should use caution when using this device.

PART 7. PREPARATION AREA

1. 701 PREPARATION AREA. This area is used for the assembly and final processing of sterile medical supplies, instruments, and equipment. Strict control of this environment is critical to attaining and maintaining a high degree of confidence in sterile item integrity. All reusable medical/surgical devices used for patient care (direct or indirect) should be sterilized in the SPD section. Reusable devices are items that are manufactured for reuse or which the manufacturer has provided specific written resterilization instructions. If, for some reason, (e.g., limited equipment, required short turn-around time) sterilizers are located in other sections of the medical facility, they will be monitored mechanically and with biological indicators. All records will be kept for 36 months for all sterilizers in the medical facility used in conjunction with patient care, e.g., lab, dental. A report of all tests and results will be submitted through the Chief, SPD, to the Infection Control Committee monthly. The preparation area attire will consist of:

a. Scrub Suits with Long Sleeves. If short sleeve scrub suits are provided, then a warm-up jacket or gown with long sleeves must be worn to cover the arms. Attire worn in this area will not be worn in other areas of SPD or the medical center without a long sleeve cover coat.

b. Head, Mustache, and Beard Coverings. Employees must wear hairnets and surgical masks to cover hair, mustaches, and beards.

c. It is recommended that shoes solely dedicated for use in SPD or the medical center facility be maintained in the employees' locker.

2. 702 ITEM PREPARATION. Single-use disposable medical devices will not be reprocessed, resterilized, or reused. The only exception to this is if the original manufacturer provides written documentation that the reprocessing of the items will not change the original intent of the item in question or the requirements outlined in part 3, paragraph 302. b. of this handbook are met. The manufacturer's instruction should be specific as to how the item should be reprocessed and other pertinent instructions, e.g., cleaning, wrapping, sterilant. If a package containing an expensive sterile disposable device is opened and the item is not used, the manufacturer will be contacted for either the possibility of exchange or specific written resterilizing instructions. In the absence of either service provided by the manufacturer, the device will not be repacked or over-wrapped and resterilized. Reusable devices should be purchased if the intent is to resterilize and reuse them. Waivers for deviation from this policy must be submitted to, and approved by, OA&MM SPD program officials prior to implementation.

3. 703 SELECT PROCESSING METHOD

a. Steam Sterilization. Saturated steam under pressure will be the method of sterilization for all items which will tolerate the temperature, pressure, and moisture. Unless specifically contraindicated in writing by the device manufacturer, steam sterilization will be the method of choice. To be effective, steam sterilization requires four conditions: proper time, sufficiently elevated temperature, sufficient moisture, and adequate contact (pressure). The time-temperature relationship is necessary to accomplish terminal sterilization in saturated steam. As the temperature increases, the kill time is decreased. Moisture is the content of the steam. Steam used in sterilization is known as saturated steam. It is necessary to have saturated steam that is 97 percent dry with 3 percent moisture content for effective steam sterilization.

Saturated steam has a constant relationship between temperature and pressure. The temperature of saturated steam cannot be reduced or increased without reducing or increasing the pressure. The minimum times to kill known quantities of the most resistant forms of microbial life at various temperatures are as follows:

(1) 30 minutes at 250 degrees F.

(2) 4 minutes at 270 degrees F.

b. Dry Heat Sterilization. Dry heat sterilization is used only for special purposes. This technique involves the use of very high temperatures that will damage most items ordinarily sterilized in healthcare facilities. The long exposure time makes the process impractical for most purposes. The only items that dry heat is appropriate for are those which cannot be sterilized by steam or EtO because they cannot be penetrated or those which will be damaged by moisture. Among the items suitable for dry heat sterilization are petroleum ointments, powders, petrolatum gauze, and other oil-based items. Sterilization of anhydrous oils, greases, petroleum jelly, powders, or similar products will not be conducted in the medical facility. Temperature settings and exposure times range from 30 minutes at a temperature of 350 degrees Fahrenheit to 12 hours at 250 degrees Fahrenheit. These times are exposure times and do not include the time needed to bring the items to the exposure temperature (temperatures vary according to the instrument structure; refer to the manufacturer's guide).

c. Flash Sterilization

(1) Flash sterilization will not be performed for the purpose of routine sterilization of surgical instruments. The flash sterilizer may be used during a surgical procedure for an unanticipated event (e.g., rises, unplanned multiple emergency procedures). It is not recommended, however, to flash large trays of instruments, such as loaner trays. Implantable devices will not be sterilized by flash sterilization. Implantable devices are any medical device that may be placed in the body, covered with tissue, and left behind. Examples of implants include, but are not limited to:

(a) K-wires.

(b) Screws.

(c) Plates.

(d) Vascular Graphs.

(e) Heart Valves.

(f) Merlex Mesh.

(g) Mercelene Mesh.

(h) Internal Pacemakers.

(i) Penile Implants.

(j) Breast Implants.

(k) Joints (such as knees, hips, and shoulders).

(2) Flash sterilizers are basically gravity displacement sterilizers set on the "open" cycle or non-wrapped cycle. The items to be flashed must be placed loosely in a tray to avoid overcrowding and should not be overloaded. It is **not** recommended that items with lumens, such as suction tubes, and power equipment be flashed sterilized, due to their complex makeup.

d. Ethylene Oxide (EtO)

(1) Sterilization by EtO will be limited to only those medical supplies and devices that might be damaged by heat, pressure, or moisture. The Chief, SPD, will develop a list of all medical supplies, devices, and equipment that require EtO sterilization and will maintain and review this list annually or more frequently, if necessary. The list will be approved by the Chief of Staff and maintained in SPD. Review will be directed at eliminating the use of EtO sterilization for material and equipment that can be effectively steam sterilized. The effectiveness of EtO depends on the relationship of four essential elements, each of which has a relationship to the other. The four essential elements of EtO sterilization are:

(a) Concentration of EtO.

(b) Humidity: Range is between 50 and 75 percent.

(c) Temperature: Range is between 85 and 100 degrees Fahrenheit (cold cycle) and 130 and 145 degrees Fahrenheit (warm cycle).

(d) Exposure Time: Exposure time is directly related to the concentration of EtO. Please consult manufacturers' recommendations for sterilizers utilizing EtO mixtures.

(2) All items processed in EtO must be thoroughly cleaned and dried prior to sterilization. If water and EtO mix during the cycle, a by-product, polyglycol, is produced. The by-product can be hemolytic, or in other words, it can destroy blood cells. Always assure that all items have been properly dried prior to sterilization.

(3) During the aeration cycle, the temperature and time are set, and warm air is circulated into the chamber for the predetermined time. During the cycle, air in the chamber is continuously evacuated out into a dedicated exhaust vent. Additional air is pumped into the chamber. This cycle continues throughout the aeration period. The supplies and instrumentation aerating must stay in the aerator the full cycle time. They must never be removed before the cycle is complete. The two accepted types of aerators are combination sterilizer/aerators and free standing cabinets. Room aeration will not be used. Aeration time is a minimum of 12 hours; some items that contain silicone may require additional aeration time. Manufacturers of these items must be consulted as to the appropriate aeration time. Aerators will not be opened until the entire cycle time has elapsed.

e. Select Packaging Method. Materials for packaging or wrapping supplies for sterilization are limited to those products specifically designed and manufactured for sterilization of medical devices. Disposable wrapping materials are single use only and must not be reused. Packaging materials must allow adequate penetration of the sterilant, must provide a barrier to microorganisms, and must allow sterile presentation of the package contents. This will allow for proper sterilization and maintaining sterility of the contents until the package is opened. Materials for packaging or wrapping supplies for sterilization are limited to muslin, disposable wraps, two-way crepe paper, non-woven wraps, spun-bond fabrics, plastic film pouches, paper/plastic combination peel pouches, and containerized sterilization systems.

4. 704 STERILIZING CONTAINERS. Containers are mainly used for surgical instrument sets and some powered equipment. Containers sometimes are used for very small sets, and they come in a variety of sizes. Containers provide added protection to surgical instrumentation and are assembled easily and quickly. Sterilizing containers must be processed to the highest level of disinfection possible prior to passing the container through to the preparation area. Sterilizing containers are processed in strict accordance with the manufacturers' recommendations. Containerized systems using valve bio-barrier configurations will not be used for gas (EtO or plasma) sterilization because the valve does not open in standard aerators and the contents of the container cannot be aerated. Filtered containers can be aerated and used in both pre-vacuum steam and gas (EtO and plasma) sterilization cycles. The container manufacturer's supporting data concerning sterilization cycle compatibility and specific instructions for use is found in section 8, Equipment Operating Instructions, of the SPD Desk Guide. Wire-type baskets are used to keep small packages in proper sterilization position. The following items will not be used:

a. Single Step Disposable Wrappers.

b. Canvas.

c. Nylon, Cellophane, Glassine, or Polyvinyl Chloride Packaging.

d. Rubber Bands to band items together for sterilization, storage, or delivery. (This applies to items processed in-house as well as sterile supplies acquired from a commercial source.)

e. Staples, Paper Clips, Pins, Tape (other than indicating tape), or similar items in conjunction with the packaging, sterilization, or storage of supplies, as they may promote accidental contamination.

5. 705 APPROVED MATERIALS AND PROCEDURES

a. Aluminum foil may be used in dry heat sterilizers only.

b. Paper/plastic peel-pouches are used only when the packages can be placed both on edge and loosely in the sterilizer to facilitate both air removal and sterilant penetration.

c. Muslin wrappers, which have been laundered, inspected for holes, and delinted between each use may be used. The minimum thread count for muslin wrappers will be 140 threads per square inch with surged edges.

d. All items wrapped in muslin, paper, spun-bond fabrics, or non-woven wraps are sequentially wrapped in two wrappers but not necessarily the same material (one after another - the final product being a wrapped package within a wrapped package). A double thickness muslin wrapper is considered a single wrap. Stitching in the body of the wrapper is not acceptable.

e. Plastic wrapping materials and combination plastic/paper laminated peel-pouches are considered to be impervious. The pouch should fit the size of the object to be placed inside.

f. Post-Sterilization Wrap Procedures. Post-sterilization wraps (dust covers) are self-sealing, heat sealed, or sealed with clear plastic tape (not to include tape utilized on patients). Chemical indicator tape will not be used for this purpose.

g. Before being placed in dust covers, steam sterilized packages must be cool and dry. Additionally, EtO sterilized items must be adequately aerated. A dust cover, if used, must be applied to a thoroughly cooled, dry, aerated package at the time the package is removed from the sterilizer or aerator carts. Caution must be taken to avoid contamination by excessive handling.

h. The dust cover must be clearly marked to indicate that it is a post-sterilization wrap or dust cover so that the outside of the inner wrap will not be mistakenly considered sterile. Identification of package contents, load control number, and expiration date must be clearly visible through the dust cover. The dust cover extends the shelf life of the items. Under no circumstances will a package have more than one expiration date. Once the package is removed from the dust cover, the extended shelf life provided by the post-sterilization wrap is no longer valid, and the package will be reprocessed.

i. Linen Packs, Instrument Sets, and Implantable Devices. Linen packs will not exceed 12 x 12 x 20 inches in size and weigh no more than 12 pounds. The density of fabric packs should not exceed 7.2 pounds per cubic foot. Special care must be taken when folding packs containing woven materials to ensure aseptic presentation and to minimize handling at the point of use. Linen packs are to be arranged in the order in which the items will be used. The layers of linen should be alternated so the folds do not all go in the same direction. This will aid in the air evacuation and steam penetration.

j. Instrument Sets. It is recommended that instrument sets not exceed 16 to 17 pounds in weight. Heavier sets may not allow sterilization and drying in the specified time because of condensation, slower heat rise, and slower heat transfer. Instruments processed in sterilizing container systems will be processed according to manufacturers' recommendations.

k. Implantable Devices. All steam and gas sterilization loads containing implantable devices will be monitored with the appropriate biological indicator. After sterilization, these devices will be quarantined in SPD and not released until the spore test is found to be negative (48 hours) unless the Chief of Staff, or designee, provides written permission for early release. Implantable devices will not be sterilized by "flash" sterilization. (The Early Release form can be found in section 11, Sample Forms, in the SPD Desk Guide.)

6. 706 ITEM IDENTIFICATION

a. All items undergoing terminal sterilization will be labeled prior to sterilization with: the common name of the package contents, the initials of the employee who prepared the package for sterilization, and the department to which the package will be sent after sterilization.

(1) Chemical indicator tape-secured packages and peel-packs are labeled by marking the necessary information on the tape using a felt-tip, indelible marker. Note: The tape will be labeled prior to placing it on the package. All chemical indicator tape will be placed on the plastic side of the peel-pack.

(2) Markings will not be made directly on the wrapper by either ballpoint or felt-tip pens as they may puncture or strike through the wrapper, contaminating the contents.

(3) Sterilizer containers may have customized identifying labels or may use indicator tape as labels. Both must have external chemical indicators, assembler's initials, lot control number, and expiration date.

b. The control number and expiration date are affixed to each package subsequent to terminal sterilization after the mechanical readings have been checked and the report is signed, the external chemical check, and the package is checked for damage. Information on lot control numbers can be found in section 1, part 3 of the SPD Desk Guide.

PART 8. LOADING/OPERATING STERILIZERS

1. 801 STERILIZER MODELS. Sterilizer models vary considerably in their performance characteristics and safety features. Therefore, any sterilizer will be operated strictly in accordance with the manufacturer's instructions. Manufacturer's instructions are found in section 8, Equipment Operating Instructions, in the SPD Desk Guide.

2. 802 STEAM STERILIZATION

a. Pre-vacuum Sterilizers

(1) This unit is connected to a steam-fed system, as well as to a steam-condensing system that converts the steam into water following the sterilization operation. The water is discharged into a floor drain. The body of the sterilizer can be encased in a stainless steel cabinet; however, the plumbing and the body of the sterilizer are usually contained in a dedicated room with only the door, control panel, and gauges visible to the staff. Processing temperature for this equipment is 270 degrees Fahrenheit. A typical pre-vacuum cycle is as follows:

(a) Phase 1 - Pre-Vacuum.

(b) Phase 2 – Exposure.

(c) Phase 3 - Come Down.

(d) Phase 4 – Drying.

(2) All pre-vacuum sterilizers will have a Bowie-Dick type test performed daily to determine if enough air is being removed from the chamber and porous load. The test will be carried out in accordance with the written instructions of the manufacturer of the test system used. Test results must be documented and maintained with the sterilizer’s records. A malfunctioning sterilizer, as indicated by the test, must be brought to the attention of the Chief, SPD, who will make the final determination on the use of that sterilizer.

b. Gravity Displacement Sterilizers. These sterilizers take longer for sterilization than pre-vacuum sterilizers. Utilizing gravity, air is gradually displaced by the incoming steam. The temperature is set at 250 degrees Fahrenheit using 30 to 34 pounds per square inch (PSI). Exposure time is 30 to 45 minutes with an added drying time of 30 minutes.

c. Liquids will not be sterilized. However, requests for deviations may be made through OA&MM SPD program officials prior to implementation.

d. Loading techniques for pre-vacuum and gravity displacement sterilizers are as follows:

(1) Instrument trays will be placed on the sterilization rack in such a manner to allow proper circulation of the sterilant.

(2) Large containerized systems or surgical trays must be placed on the bottom rack, while smaller trays or sets and individual packages must be placed on the top rack. If large sets are placed on the top rack, condensation during the sterilization cycle may form on the larger sets and drip onto the smaller items, causing staining of the packages. Staining may be an indication of a contaminated package.

(3) Linen packs and basin or utensil sets will be processed separately from the surgical instrument sets. If this is not possible, the linen items will be placed on the top rack of the sterilization cart and the instrument sets on the bottom rack. Limit mixed loads as much as possible. Mixing muslin or linen items with instruments can cause staining of the surgical instruments. Pouches will be placed on edge in a mesh-bottom basket.

(4) If the load is to be biologically monitored, the test pack is placed in the lower portion of the chamber, near the door, in an otherwise routinely loaded sterilizer.

e. Unloading techniques of pre-vacuum and gravity displacement sterilizers are as follows:

(1) After the sterilization cycle is complete, the door will be cracked open for a period of 15-minutes in order to equalize the sterilizer chamber temperature with room temperature. Doing so will prevent condensation from forming on the packages.

(2) The sterilizer cart is removed from the sterilizer and placed in a sterile holding area, or other low traffic area, where it should remain until the load is cool and dry. The cart should not be placed near air vents because air currents may cause condensation to form. Never touch sterile items while they are cooling. Hot packages will quickly absorb moisture. As a result, bacteria that live on hands may be wicked into the package, thus contaminating the contents. Do not place freshly sterilized items on metal or cold surfaces before they have cooled adequately. When hot and cold surfaces are brought together, condensation will form. Consequently, the contents will be contaminated.

(3) When the cooled items are removed from the sterilizer cart, they must be visually inspected. Any item on which packaging appears to be torn, stained, or wet will be reprocessed. Linen packs should be disassembled and relaundered. All linen items must be laundered between sterilization to rehydrate them.

3. 803 GAS STERILIZATION. Manufacturers and SPD officials recommend that aeration/combination sterilizers be used to reduce potential EtO exposure. The operating procedures of each type of EtO sterilizer vary among manufacturers. Specific operating instructions can be found in section 8 of the SPD Desk Guide.

a. 100 percent EtO-EtO/CFC-EtO/CO2 EtO Mixtures. Sterilization by EtO will be limited to only those medical supplies and devices that might be damaged by heat, pressure, or moisture. Two types of Ethylene Oxide sterilizers most commonly used are "single dose" cartridges of 100 percent Ethylene Oxide and larger units that typically use tanks or cylinders of EtO diluted with hydrochloroflorocarbon or carbon dioxide.

b. Loading and Unloading EtO Sterilizers. Both types of EtO sterilizers are loaded and unloaded in the same manner. Packaged items to be sterilized should be placed on metal sterilizer carts or in wire baskets. The use of metal carts or baskets minimizes handling of sterile items and, because metal does not absorb Ethylene oxide, allows safe transfer of the items from the sterilizer to the aerator if necessary.

(1) When the cart or basket is loaded, the items to be sterilized are arranged loosely to ensure that the sterilant will circulate freely and reach all surfaces. The items must be arranged so that they will not touch the sterilizer chamber walls during the sterilization cycle or the operator's hands when they remove the load from a sterilizer for transfer to the aerator. Heavy packages will not be stacked, and pouches will be placed on edge.

(2) When technicians unload non-combination EtO sterilizers, sterilizer carts will be pulled, not pushed, to the aerator so that the technician can avoid inhaling EtO that has been absorbed by the sterilized items. Approved self-contained respirators and Butyl gloves will be worn to protect the technician from contact with any residual EtO. After use, the gloves will be aerated.

(3) Every load will contain a biological indicator. The biological indicator will not be removed from a combination sterilizer/aerator until the end of both cycles, but may be removed while transferring the load from a non-combination EtO sterilizer to an aerator.

c. Warm/Cold Cycles. Some items are so heat sensitive that they require a lower cycle temperature. This is accomplished by reducing the operating temperature and lengthening the exposure time. Cold cycle ranges are approximately 100 degrees Fahrenheit (33 degrees Celsius) and warm cycles are approximately 130 degrees Fahrenheit (55 degrees Celsius). Exposure required for cold cycles is approximately 4 hours, and for warm cycles it is approximately 1 hour and 45 minutes; this may vary per the manufacturer’s instructions.

d. Aeration Techniques. In a typical aeration cycle, the temperature and time are set and warm air is circulated into the chamber for the predetermined time. During the cycle, air in the chamber is continuously evacuated into a dedicated exhaust vent. Additional air is pumped into the chamber. This cycle continues throughout the aeration period. The supplies and instrumentation being aerated must stay in the aerator the full cycle time. They must never be removed before the cycle is complete. The two accepted types of aerators are combination sterilizer/aerators and free standing cabinets. Room aeration will not be used. Aeration time is a minimum of 12 hours; some items that contain silicone may require additional aeration time, such as items containing silicone. Manufacturers of these items must be consulted as to the appropriate aeration time. Aerators will not be opened until the entire cycle time has elapsed.

4. 804. DRY HEAT STERILIZATION. The use of dry heat as a sterilization method is not recommended. Sterilization of anhydrous oil, greases, petroleum jelly, powders, or similar products will not be conducted in the medical facility. Any deviation from this policy will require a waiver. The waiver must be submitted to and approved by OA&MM SPD program officials prior to implementation.

5. 805 LIQUID CHEMICAL (COLD) STERILIZATION. Examples of liquid chemical sterilization include, but are not limited to: glutaraldehyde, phenolic compounds, alcohol, quatenary compounds, and iodine. There is no present method available that allows the user to microbiologically test the efficacy of a liquid chemical sterilization process within the healthcare

facility. Therefore, liquid chemical and cold liquid sterilization processes may be employed for high level disinfection only. The manufacturer's recommendations for the solution to be used will be followed. Terminal sterilization by this method is not authorized.

6. 806 CHEMICAL STERILIZER. Sterilization by paracetic acid will be limited to medical devices that are sensitive to extremes in temperature and pressure. This method of sterilization for items used in surgery will be used only as a flash sterilizer and only when needed for an emergency, when normal (steam or EtO) sterilization cannot be used. Items that should be sterilized between patient use, such as non-invasive flexible endoscopes, but do not have to be sterilized for use, should be cleaned and processed in SPD.

7. 807 PLASMA STERILIZER. Plasma sterilization is an alternative to EtO sterilization for those items that cannot withstand high temperatures and moisture. There are limitations per FDA approval and label copy as to what can be sterilized with plasma. Weaknesses also include biological monitoring and the effect that bioburden has on this sterilization method. Plasma is not considered toxic, which reduces the need for aeration and eliminates the requirement for personal monitoring. Due to the lessened, or lack of, aeration time, turn-around time is significantly reduced. FDA label copy for plasma systems is limited. It is strongly recommended that each medical center validate and document that medical devices are approved for sterilization by this method. The manufacturer of the medical device should provide this documentation.

8. 808 STERILIZER MONITORING

a. Mechanical Monitoring

(1) A register will be established for sterilizing equipment without an automatic recording device. The sterilizer operator will record the following information for each sterilizing cycle:

(a) Sterilization date.

(b) Time the cycle was started.

(c) Time sterilization phase began.

(d) Sterilization temperature.

(e) Actual length of sterilizing cycle at desired temperature (exposure period).

(f) Remarks (e.g., condition of load, sterilizer breakdown).

(g) Signature of sterilizer operator.

(2) For all sterilizers equipped with a recording device, the appropriate chart or digital printout will be examined and signed by the sterilizer operator after each cycle, before any items are removed from the sterilizer to verify adequate temperature and duration of exposure.

(3) For all sterilizer loads, the control number assigned and a register of contents as to general category (e.g., linen packs, instruments, respirator care supplies) will be maintained. This register will be critical in the event that a recall is necessary due to sterilizer failure. This register will be maintained, along with other sterilization records, for a period of 36 months.

(4) Sterilizer malfunctions or suspicious operation, as indicated by the recording device, will be reported immediately to the Chief, SPD. He/she will make the final determination on the use of that sterilizer, initiate an appropriate request for service, and implement reprocessing routines for the load in question.

b. External Chemical Indicators. A strip of the appropriate sterilizer indicating tape must be affixed externally to each package prior to terminal sterilization. This indicator tape, label, or legend indicator visually denotes that the package has been exposed to the physical condition of a sterilizing cycle, but will not be considered evidence of sterility. The indicator must be examined after sterilization to make sure it indicates that the item has been processed.

c. Internal Chemical Indicators. The use of internal chemical indicators is optional based on local consideration of the costs versus the benefits. Internal chemical indicators are not sterility indicators and will not be used as a substitute for biological indicators. The person recovering the indicator from the sterile pack must be adequately trained in the interpretation of the specific indicator used. Written supporting data from the manufacturer of the internal indicator used at the medical center regarding indicator reliability, safety, efficiency, performance characteristics, instructions for use, and interpretation of results are found in Section 8, Equipment Operating Instructions, in the SPD Desk Guide. Instructions for appropriate use, placement, and interpretation of results must be communicated to the product users by the Chief, SPD, and the instructions will be revised as necessary.

d. Bowie-Dick type Test. This test is to determine adequacy of air removal from chamber and porous load, will be performed daily for each pre vacuum (high vac) steam sterilizer. The test results will be recorded on the sterilizer-recording chart. If commercially prepared test products are used, the test will be carried out according to the written instructions of the manufacturer. In the absence of commercial products, test packs will be prepared in the following manner:

(1) Eighteen surgical towels will be folded in fourths, assuring that they are all folded in the same manner.

(2) A plain piece of paper with strips of steam chemical indicator tape will be placed in a criss-crossed pattern extending from edge-to-edge of the paper. The paper will be placed between the towels, with 9 on top and 9 on bottom, wrapped and placed in the bottom front of the sterilizer, above the drain.

(NOTE: Medical supply technicians must be trained in test preparation and interpretation of Bowie Dick tests. Test results must be documented and maintained with the records of that sterilizer.)

e. Biological Monitoring.

(1) Each sterilizer will be biologically monitored at least once every day that the sterilizer is used, with each load containing an implant, with each gas load, and with the first load after a repair. The biological test will be run with a normal load. Commercially prepared self contained biological monitors will be used when available. Bacillus stearotermophilus (Geobacillus Stearothermophilas) spores will be used to monitor steam sterlizers. Bacillus subtilis (Bacillus Atrophaeus) spores will be used to monitor dry heat and gas sterilizers. Each day a test is run, one control per lot number of the biological monitor used will be processed (a control is a biological test which has not been subjected to the sterilization process and is incubated to make sure that the bacillus is alive.) Biologicals will be placed in an incubator immediately after the load has completed and cooled. When a positive biological test result is obtained, the biological indicator will be immediately submitted to the microbiology laboratory for a presumptive organism identification. This helps to determine if the living microorganism is the indicator test microorganism (indicating inadequate sterilization conditions) or if an accidental contaminant could have been introduced after the load was removed from the sterilizer. If spores are not killed in routine spore tests, the proper use and function of the sterilizer will immediately be checked. All items processed in the sterilizer since the last negative test will be recalled for a positive test. The sterilizer in question must immediately be rechallenged with biological indicators. If spore tests that remain positive after proper use of the sterilizer are documented and an operational inspection has been performed, use of the sterilizer will be discontinued until it is serviced. Positive biological indicator results will be reported immediately, in writing, by the Chief, SPD, to the: Chief of Staff; Chief, Surgical Service; the service responsible for the SPD section; and the Infection Control Committee. The report will include the time and date of the questionable sterilizer cycle; description of the sterilizer and load, with reference to the appropriate load control number; time and date of notification of positive results; laboratory identification of the organism; and any other pertinent information. The Chief, SPD, will make recommendations to the Chief of Staff; Chief, Surgery Service; and the service responsible for the SPD section, for further action as considered appropriate or necessary. In all cases, the sterilizer in question must immediately be rechallenged with biological indicators.

(2) A **rapid readout** biological may be used in the pre-vac steam sterilizers with **wrapped** supplies. A reading may be taken at 3 hours, and the results must be recorded. ***However, the biological must remain incubated, be visibly read, and the results must be recorded at 48 hours*.** This may be helpful in providing information to the Chief of Staff when requesting early release of an implantable device from quarantine. The results of the biological reading will be reported to the Chief of Staff at 48 hours. No biological reading will be taken in less than 3 hours. Rapid readout biological monitors are not to be used in **flash sterilizers**. Flash sterilizers are to be used in an emergency when other methods of sterilization are not available. (If the item sterilized can be held for 1 hour, it must be sterilized in a package.)

NOTE: The 1-hour biological monitor for flash sterilizers has not been approved for use in VA.

f. Fluid Monitoring. SPD will not manufacture or sterilize parenteral or irrigating solutions. Hospitals are not equipped to monitor fluids to assure sterility and non-pyrogenicity in accordance with current Food and Drug Administration requirements.

9. 809 STERILIZATION PROCESS CONTROLS

a. All reusable medical/surgical devices used for patient care (direct or indirect) should be sterilized in the SPD section. Reusable devices are items which are manufactured for reuse or for which the manufacturer has provided specific written resterilization instructions. If, for some reason (e.g., staff, limited equipment, required short turnaround time), sterilizers are located in other sections of the medical facility, they will be monitored mechanically, chemically, and with biological indicators.

b. All records will be kept for 36 months (this includes records for all sterilizers in the medical facility used in conjunction with patient care, i.e., lab, dental). A report of all tests and results will be submitted monthly through the Chief, SPD, to the Infection Control Committee.

c. A standard operating procedure will be instituted by the Chief, SPD, and, when necessary, coordinated with Laboratory Service for the routine challenge of each sterilizer by means of a commercially prepared, self-contained biological monitoring system. Bacillus stearothermophilus spores will be used to evaluate steam sterilizers. Bacillus subtilis spores will be used to evaluate dry heat and gas sterilizers. Each steam or dry heat sterilizer will be tested a minimum of once daily on days that the sterilizer is utilized. Gas (EtO and plasma) sterilizers will be tested with each sterilizing cycle. Chemical sterilizers, such as Steris, will be biologically monitored at least once per day on the days that the sterilizer is used. More frequent testing will be performed on an as-needed basis for record purposes (e.g., after sterilizer repairs, when evaluating sterilization new products, packaging materials). One control from each lot of biological tests will be used for gas, steam, and chemical sterilizers each day. All biological monitoring test results will be interpreted and recorded at 48 hours. It is recommended that the Chief, SPD, or designee, in strict conformance with the manufacturer's instructions, interpret biological test results. Advice of Laboratory Service will be solicited on any questionable results following use of a self-contained biological monitor. Written test results of all biological monitoring will be maintained with the sterilizer records and kept on file in SPD for 36 months.

d. All sterilizer loads containing implantable devices or intravascular materials will be monitored with the appropriate biological indicator. After sterilization, these devices will be held in quarantine by SPD and will not be used until the spore test is found to be negative after 48 hours. Early release for use will be permitted by the Chief, SPD, only after documentation is obtained from the Chief of Staff, or designee. Implantable devices will not be sterilized by flash sterilization.

e. When a positive biological test result is obtained, the biological indicator will be immediately submitted to the microbiology laboratory for a presumptive organism identification. This helps to determine if the living microorganism is the indicator test microorganism (indicating inadequate sterilization conditions) or an accidental contaminant that could have been introduced after the load was removed from the sterilizer. If spores are not killed in routine spore tests, the proper use and function of the sterilizer will immediately be checked. All items processed in the sterilizer since the last negative test will be recalled for a positive test. The sterilizer in question must immediately be rechallenged with biological indicators. If spore tests remain positive after proper use of the sterilizer is documented and an operational inspection has been performed, use of the sterilizer will be discontinued, and it will be serviced.

f. Positive biological indicator results will be reported immediately, in writing, by the Chief, SPD, to the Chief of Staff; Chief, Surgical Service; the service responsible for the SPD section; and the Infection Control Committee. The report will include the time and date of the questionable sterilizer cycle; description of the sterilizer and load, with reference to the appropriate load control number; time and date of notification of positive results; laboratory identification of the organism; and any other pertinent information. The Chief, SPD, will make recommendations to the Chief of Staff; Chief, Surgery Service; and the service responsible for the SPD section, for further action as considered appropriate or necessary. In all cases, the sterilizer in question must immediately be rechallenged with biological indicators.

g. Not later than the 10th day of each month, a written report of biological spore tests conducted on all sterilizers during the previous month will be submitted to the medical facility Infection Control Committee by the Chief, SPD. This report will include the total number of biological tests and controls conducted on each sterilizer and the results of that testing. The Chief, SPD, is responsible for biological monitoring and reporting on all sterilizers that process items used for direct or indirect patient care. For sterilizers that are located in areas other than SPD, the Chief, SPD, will provide training and assistance as needed to complete the monitoring and reporting described above.

10. 810 LOT CONTROL NUMBER. A six-digit control number will be assigned for each sterilizing cycle. The first digit identifies the numerical designation of the sterilizer being used. The second, third, and fourth digits indicate the Julian calendar day of the year, i.e., 001 through 365 days. The fifth and sixth digits refer to the number of sterilizer cycles per 24-hour period.

For example, if an item was sterilized in autoclave number 3 on March 5, 1998, in load number 4, then the lot control number would be 306404. An item sterilized in autoclave number 2 on July 5, 1998, in load number 11 would have the lot control number of 218611. The lot control number is affixed to an item after sterilization, and the mechanical and chemical tape indicators are checked. This is to insure that all parameters have been met.

11. 811 ITEM EXPIRATION

a. Shelf life refers to the time that an item can remain on a shelf and still be safe for patient care use. There are many things that can affect the shelf life. Sterility is event-related, not time-related; however, the packaging material can affect shelf life. If the package is breathable (e.g., muslin, paper, and non-woven materials), handling and airflow may compromise shelf life. Shelf life is also affected by the contents within the package, such as plastics, rubber, medication, and metal instruments that may rust, corrode, or become stiff with time. This applies to both commercially packaged products as well as those items processed within the medical center. Shelf life also aids in inventory control by reducing the amount of on-hand inventory and increasing turnover rate. Items that are processed in the medical center are very expensive. Any items that are outdated will be reviewed; the using service will determine if there is still a valid need for that item. If the item is no longer required, it can be excessed.

b. Guidelines for shelf life for the following items:

(1) Woven/non-woven wrapped items with no dust cover 30 days

(2) Woven and non-woven wrapped items with a dust cover 1 year

(3) Paper/plastic peel pouch 1 year

(4) Containerized systems 1 year

c. Commercially sterilized items usually carry an indefinite shelf life. It is indicated on the label that the contents are sterile unless the package integrity has been compromised.

d. All SPD-processed items remaining on the shelf for 12 months must be pulled and reprocessed.

PART 9. DISTRIBUTION

1. 901 INTRODUCTION TO DISTRIBUTION. The medical and surgical supplies inventory for the medical center must be managed in a centralized distribution area. The distribution area of SPD performs a major role in not only getting the correct supplies and equipment to users but also in assuring that these supplies are in the correct quantity, quality, location, and condition for use. This allows clinical staff to spend their time on patient care needs. It also allows large volume purchases and fewer orders to process, which saves the medical center time and resources.

a. One of the most visible ways to maintain an aseptic environment is to wear the proper attire. Wearing proper attire helps protect the supplies from outside contaminants that street clothes may bring in. The clean/sterile storage area should be divided into two sections: one section for clean/sterile supplies used on wards and treatment areas of the medical center, and one section for the surgical case carts and/or supplies that will be used in the operating suite. The attire for the case cart section is the scrub suit, the same worn in the preparation room, and hair covering. The attire for the other section of the clean/sterile storage room is white pants and a blue smock. If it is necessary for staff wearing the white pants and blue smock to enter the case cart section, they must put on a cover gown and hair covering. Medical center personnel entering the clean/sterile storage area wearing other clothing must wear a cover gown. SPD staff wearing scrubs, who work in the case cart area, must wear a lab coat or cover gown when leaving the case cart or preparation area. In every possible way, SPD's first concern is to follow procedures and techniques to prevent the spread of infection.

b. Cosmetics, drinks, and food in SPD are prohibited. Such items may spill, causing contamination, or spoil, encouraging microorganism population growth and endangering valuable medical supplies.

c. Items are sent to the user areas via closed carts, exchange carts, covered carts, dumb waiters, and pneumatic tubes or are hand-carried in impervious bays or containers. All *stat items* are hand-carried to ensure that these items are delivered promptly to the area in the critical time of need. Care must be taken to ensure the sterility of medical supplies and equipment when transporting these items to delivery points throughout the medical center. Covers must be impervious and completely surround the cart, bin, or item.

d. Medical supply technicians have the responsibility of stocking all user areas with patient care supplies and equipment. Supplies are stocked on a regularly scheduled basis in supply closets or nurse servers on each unit.

2. 902 TYPES OF DISTRIBUTION

a. When clean and sterile supplies are needed in the user areas of the healthcare facility, they must be transferred from the SPD department to the point of use. There are five main types of distribution systems available that may be used to ensure that the correct product is delivered in the right condition and on time. The type of system used depends on the services the healthcare facility provides, its size, physical design, age, resources, and mission. The systems are as follows:

(1) Demand Distribution System

(a) Every healthcare facility has used the demand distribution system (also known as a requisition and delivery distribution system) at one time or another. In this system, the staffs of various user areas are responsible for maintaining an adequate level of supplies for use in that area. When supplies must be replenished, or an individual item is needed, the user must prepare a requisition and request the necessary items, usually by telephone or in person. The SPD staff fills the order and delivers it to the user area by dumb waiter or in person. After delivery of the items, the requesting user is responsible for storing the items or transferring them to the point of use. This distribution system is generally carried out on a regularly scheduled basis or as needed, hence the term "Demand" Distribution System.

(b) The Demand Distribution System is a simple process and has fulfilled supply needs for the healthcare facilities for many years. There is a tendency to maintain high levels of stock (hoarding) in the user area to eliminate frequent requisitioning and documentation. Maintaining excessively high inventories can be very costly to healthcare facilities. The disadvantages of the demand system are as follows:

1. The method is very labor-intensive. It is generally unsuitable for high-volume distribution in a large facility.

2. Personnel in the user areas generally have patient care responsibilities and other priorities and do not have the time or the training to commit themselves to do adequate inventory control.

(2) Par-level Restocking Distribution System.

(a) In this type of system, an inventory or par-level is set for each stocked item used daily. These levels should be reviewed frequently and changed as necessary to reflect actual usage. The SPD technician is responsible for reviewing the levels daily as stock is being inventoried and maintained. The SPD technician should communicate with the customers in order to make necessary changes based on patient care needs. Supply closets, treatment rooms, and nurse servers are used for storage of these supplies.

(b) A typical procedure to maintain stock in the areas is to assign a technician to each area(s). The technician will inventory all supplies in the treatment rooms, supply closets, and other areas where supplies are stocked. The technician will return to the SPD department and fill in the inventory sheets or have them filled by other technicians. When the supplies have been obtained, the technician then replenishes the user area with the preset "par-levels." Healthcare facilities utilizing nurse servers for patient care supplies also use a par-level restocking system.

(c) A listing of all needed supply items and levels are posted on the inside of the nurse servers; therefore, the user and the SPD technicians will know what should be readily available at all times for patient care. The nurse servers are stocked with supplies as needed to bring supply levels up to "par" or preset levels. Nurse servers are usually restocked from a mobile supply cart that contains all needed supplies. This cart is inventoried and restocked daily by the SPD technician. The par-level system is user-friendly in that the users no longer have the time-consuming task of maintaining their own supply inventory, and inventories can be maintained at more optimum levels than in the demand system. In most healthcare facilities, this system provides an excellent means of tracking the use of patient care items.

(d) The disadvantage of this system is that distribution is a timely process if the healthcare facility is large or spread over several areas. Some medical centers use a replenishment cart, which the SPD technician takes to each area for restocking medical supplies to par-levels. This procedure may require the technician to return to the SPD department frequently for restocking the replenishment cart.

(e) Point-of-Use Equipment. Point-of-Use (POU) equipment is an automatic dispensing system that provides secured storage of supplies close to where the supplies are used. Access to supplies is limited to employees who are provided passwords. The use of POU should be considered for areas with high cost and high volume to track actual costs to patient or procedure. These units may also have potential for remote clinics and areas where inventory managers are not assigned, such as community based outpatient clinics. The POU equipment not only allows for tracking usage, but also reduces the consumption and loss of products.

(3) Exchange Cart System

(a) The exchange cart system, like the par-level restocking system, has pre-set levels that have been established by the user and the SPD technician. In the exchange cart system, two identical carts are stocked with supplies. Once the levels of these carts have been established, one cart is placed in the user area and one in SPD. On a regular basis, the cart in the user area is returned to SPD and the identical (fully stocked) cart in SPD is exchanged in its place.

(b) The exchange cart system is practical, flexible, dependable, easy to manage, and can be used in all healthcare facilities. This system allows for thorough documentation, good control of patient care supplies, and identification of lost stock. This distribution system can be extremely cost-effective through its control of inventory, timesaving, and manpower. The disadvantages of this system are that duplication of stock and large amounts of space are needed for storage and handling of carts in the SPD distribution section. The cost to establish this system can be very expensive due to the initial purchase of the exchange carts and the additional inventory required to stock them.

(4) Case Cart System

(a) In the case cart system, the operating room is provided with selected supplies for each surgery via a case cart system. These case carts have supplies and instruments that will be used for individual cases. The supplies and instruments for the case cart system can be

provided by different methods, such as procedure cards, computer printouts, and requisition forms. The method used most frequently is the computer printout. In this method, each surgery is generally assigned a computer number by SPD. The surgery schedule is given to the SPD computer operator who generates a case care listing for each surgery. When surgery receives the schedule, a computer number is assigned to each case accordingly. These computer case cart sheets are given to the SPD technician who fills the case carts with supplies and instruments that are located in SPD. The case carts are filled according to the time the surgery is scheduled for the next day. All scheduled first case carts are delivered and placed in the operating room or clean corridor until time for use. All other case carts are delivered to the operating room at the time of need. At the completion of the surgery, all contaminated supplies are placed within the soiled holding area. The carts are retrieved by SPD personnel and taken to the decontamination area for reprocessing.

(b) A major advantage for using the case cart system is the efficiency and cost savings that can be gained by concentrating processing and inventory management expertise and equipment in SPD. Another advantage is the improvement of patient care during surgical intervention. By removing non-nursing activities, the nursing staff can spend more time on patient care and implementation of the nursing process. Patient care and employee safety can be enhanced by the effective infection control that the case cart system provides. Using a separate cart for each case can provide confinement and containment. A closed case cart system provides for enhanced infection control. The implementation of a case cart system avoids costly duplication of effort, equipment, and inventory. When case carts are prepared for each procedure, there is better control of inventory which results in cost savings.

(c) Case carts allow the turnaround time for instrument processing to be reduced. Initially, instrument inventory may need to be increased in order to implement the case cart system. One other factor to be examined before initiating a case cart system is the proximity of the surgical area to SPD. The most desirable scenario is to have the SPD department area located either adjacent to the operating room or one level above or below. If possible, a dedicated transport system between the operating room and SPD should be planned for transfer of supplies and equipment. The same procedures for traffic control and dress attire should be adhered to in SPD preparation areas as in the operating room.

(5) Specialty Carts

(a) Specialty carts are carts that contain supplies needed in emergency or special situations. Specialty carts include the following: disaster, implant, crash or code carts, and special procedure carts, such as arterial line, central line, Swanz Ganz, urology, and suture.

1. Disaster carts are stocked with medical supplies needed for use in emergencies (internal/external disasters) such as a large traffic accident, bombing, or flood. These supplies should be stocked on a cart that can be easily transported to the scene of the disaster. Transportation of the carts should be conducted in a manner so as not to compromise the medical supplies contained within the cart. It is recommended that the contents of disaster carts be reviewed and updated as needed or, at minimum, on an annual basis.

2. Implant carts are stocked with implants, such as intraocular lenses, vascular grafts, and knee and hip prostheses that are transported to the operating room at the time of surgery.

3. Crash or code carts are specialty carts used in emergency situations to revive victims from respiratory failure or cardiac arrest. SPD personnel stock these carts with medical supplies, and the pharmacy department stocks drugs and intravenous solutions. Code or crash carts containing supplies and drugs are to be kept locked to secure their contents. Filled crash carts are maintained throughout medical facilities so that they can be utilized quickly during emergencies. Backup crash carts are readily available in SPD for exchange when one is used. The outside of the code or crash cart should be inspected daily by hospital personnel to ensure the security of the cart and exterior supplies and equipment. The outside of the code or crash cart will contain a listing of all supplies that are needed. The outside of the carts should be checked daily for drug expiration dates. SPD employees should read the policy and procedures manual at their VA medical center to know their role and what is expected of them during an emergency situation.

(b) Specialty carts will be cleaned between use, or as needed, and brought to the receiving area of SPD. Contents will be removed and inspected before taking the cart to the decontamination area for processing. ***Under no circumstances*** will medical supplies be taken into the decontamination area. Any item taken into the decontamination area must be considered contaminated. Any item that cannot be reprocessed (i.e., single use or disposable items) will be disposed of.

(c) Specialty cart inventories should be reviewed routinely, and product usage should be communicated to the user. This will reduce the potential for waste (time and resources).

(d) Nurse Servers are small double door cupboard in the wall of patient rooms to store supplies for patients in each room. The server is stocked from the hallway, and supplies are removed for use from inside the room. The doors to nurse servers are to be closed at all times.

b. The type of system used depends on the services the healthcare facility provides, its size, physical design, age, resources, and mission. SPD management may periodically reevaluate their distribution systems in order to meet the current demands placed on the facility (e.g., census, finances). The important considerations in evaluating a distribution system are whether it provides information on future supply needs, the timeliness and accuracy with which supplies can be made available to the user, and how the system provides for control and documentation of inventory movement. It is important that the technicians be familiar with the characteristics, advantages, and disadvantages of each type of distribution system. This way they can better understand why a particular system is used at their medical system and how they can help make their distribution system as cost-effective, reliable, and efficient as possible.

3. 903 DELIVERY METHODS AND EQUIPMENT. Several methods and types of equipment are used to deliver and store medical supplies. Distribution carts are used to transport and store supplies. Dumbwaiters and other mechanical devices are used to transport small quantities of supplies to the point of use upon request. In emergency situations, SPD personnel may be

requested to deliver items "stat" ("stat" meaning immediately). "Stat" supplies will be delivered by the fastest method available, preferably hand deliverey. Hand delivery will ensure the needed items reach the point of use as soon as possible. Mechanical devices cannot ensure that "stat" items reach their destination, due to a possible power failure or electrical outage. Users can obtain items directly from SPD. This is called window distribution, which is utilized by some healthcare facilities.

4. 904 DISTRIBUTION WORK PRACTICES. SPD personnel must remember that careful handling and timely delivery of supplies are needed in the patient care area. If not, the user may lose confidence in SPD services. This will cause the users to hoard supplies resulting in duplication that can be costly. Patient care can be adversely affected if the right item is not delivered, in the right condition, at the right time, and ready for use.

5. 905 SELECTION OF ITEMS FROM INVENTORY. The distribution process begins when a request is received for supplies or equipment. These items should be handled carefully to avoid damage or contamination. The type and quantity of items should be verified before transporting them to the point of use. All items used in or distributed by SPD must be checked for expiration date and external chemical indicator (to verify the item was subjected to the sterilization process). In addition, all packages and items will be inspected to ensure that the packaging is not damaged, wet, or soiled.

6. 906 DELIVERY OF ITEMS TO PATIENT CARE AREAS. During transport, clean and sterile supplies must be covered or enclosed to protect the supplies from the environmental hazards. Distribution carts, which are used for the transport of sterile supplies, must have a barrier or solid bottom shelf protecting the supplies from the wheels and floor. Items that fall on the floor during transport must be inspected for damage to determine if there is a need for reprocessing or disposal. Clean/sterile supplies will never be transported on the same carts or in the same containers as contaminated supplies. Each VA medical center will implement a transportation system in order to keep clean/sterile items separate from contaminated items. After the clean supplies are delivered, soiled materials will be returned to the decontamination area in the same cart/container. Carts must be cleaned prior to reuse for clean supply delivery. SPD personnel must use caution when transporting heavy carts and must use proper body mechanics to avoid injury. SPD technicians will never leave distribution carts unattended. Leaving carts unattended could cause patient/employee injury, loss or theft of supplies, and contamination of sterile supplies.

7. 907 EQUIPMENT TRACKING. Each VA medical center has a procedure for tracking medical equipment. Some facilities track equipment by using a pegboard, cardex, alphabetical file, or computer system. Each piece of equipment should be accounted for, and safety inspections must be completed when required. Equipment should never be delivered to the point of use if it has not been inspected or is not functioning properly.

PART 10. SPD INVENTORY

1. 1001 MANAGEMENT OF INVENTORY WITHIN SPD OR PRIMARY/SECONDARY LOCATIONS

a. Inventory management is the process by which the right product is delivered at the right time, in the right condition, and ready for use, by utilizing resources in the most efficient manner. Inventory management is the responsibility of each and every employee. Controlling inventory management through standardization of products, reducing waste (time and resources), competitive procurement, and the elimination of unofficial stagnant inventories has a tremendous impact on cost containment.

b. Standardization of medical supplies and equipment at the medical center is very important to deter the rapidly rising cost and duplication of medical supplies. The Commodity Standardization Committee and related subcommittees review and evaluate products for use in the medical center in order to maintain a state-of-the-art and quality medical service, as well as to reduce the number, sizes, kinds, and grades of items.

2. 1002 AUTOMATED INVENTORY

a. The inventory management program utilized by VA consists of IFCAP (Integrated Funds Distribution, Control Point Activity, Accounting, and Procurement) and GIP (Generic Inventory Package). The IFCAP inventory system is used to manage the receipt, distribution, and stock maintenance of items received from the supply warehouse and/or outside vendors in accordance with VHA Handbook 1761.2. IFCAP provides information on supplies, equipment, vendors, procurement history, and control point activity.

b. GIP is a portion of IFCAP used to manage inventory within SPD using areas. GIP consists of primary inventories and secondary inventories. The primary inventory is the SPD inventory, and the secondary inventories are the points of distribution. Other types of primary inventories within the medical center include Pharmacy and Warehouse. Within GIP, the SPD inventory (primary inventory) consists of all items stocked and/or procured by SPD. Stock levels are established to maintain constant availability of items. These stock levels are:

(1) Normal Stock Level - represents the largest amount of an item to be maintained in the primary (on SPD shelves).

(2) Standard Reorder Point Level - represents the level at which the item is to be reordered.

(3) Optional Reorder Point Level - alerts you that the level of an item has fallen below the normal stock level but has not yet reached the standard reorder point level. This allows you to include items very near their reorder point in upcoming purchases with the same vendor, thereby reducing separate purchases to the same vendor within short periods of time.

(4) Emergency Stock Level - represents the smallest amount of an item to be maintained in the primary. This level alerts you that an emergency purchase is required.

c. GIP has the ability to "autogenerate" orders. This is where the computer automatically reviews preset inventory levels against current amounts on hand and identifies those items below the preset levels in order that they may be requisitioned.

d. Computerized bar code labels identify each item within the inventory. The medical supply technician uses a bar code reader to scan the label to identify the item and then enter the actual amount present. After scanning a secondary inventory, the information is uploaded into GIP, and a picking ticket is generated. The picking ticket identifies the items and amounts required to be restocked in that secondary to return to preset levels.

e. All inventories maintained in user areas are called secondary inventories. Within GIP, secondary inventories are also maintained with stock levels and reorder points. Secondaries may be maintained by SPD or the user. The normal stock level and the standard reorder point level should be the same in the secondaries. This assures that supplies are maintained at the established user requirement level. Primary and secondary inventories are reviewed on a regular basis utilizing GIP-generated reports, including but not limited to:

(1) History of Distribution Report - shows the total dollar amount of supplies distributed to each secondary. This information is useful in computing quarterly and annual budget reports and compiling a Cost Distribution Report (CDR).

(2) Inactive Item Report - gives a list of items for a specific period of time that have been inactive, allowing a determination to be made as to whether an item should continue to be stocked.

(3) Usage Demand Analysis Report - used to evaluate item usage and show an increase/decrease in usage, thus indicating a need to change stock levels.

f. Alternative distribution systems are available for use by medical centers to meet specific stock requirements, to ensure product availability, and to reduce waste (time and resources). Every effort will be made to have all items available at all times; a 100 percent fill rate is expected. Hospitals that are in close proximity may borrow items in times of emergency. Some of these systems include:

(1) Consignment. A vendor maintains a portion of the primary inventory on the shelves and bills the medical center once a month for items used during that period. Consignment is considered a "no cost" inventory program because the medical center pays nothing until items are used. In addition, many times the vendor will purchase the inventory on hand delineated as consignment items, thereby producing a substantial influx of funds.

(2) Prime Vendor. A single vendor serves as distributor for a portion of the SPD primary inventory, regardless of brand or manufacturer. They provide next-day delivery which allows SPD to greatly reduce the amount of stock on hand.

(3) Stockless. A system where there is no primary inventory. Vendors deliver stock on an as-needed basis, prepackaged, 2-3 times per day, 7 days a week.

g. It is important to avoid overstocking and understocking in both the primary and secondaries. Overstocking ties up a considerable amount of money in stock and increases the risk of damage, outdating, contamination, or obsolescence of the item. Understocking creates the risk of unavailability of supplies, which affects the quality of patient care. It also creates additional purchase costs (overnight shipping) and adversely affects the trust users have in SPD.

h. All clean and sterile storage areas will be designed to promote cleanliness, visibility, safety, and efficiency of distribution. The inventory should be verified on a regular basis for outdated items and damaged or obsolete items. The rotation of stock is vital to prevent unnecessary outdates and additional costs.

3. 1003 Environmental Control of Storage Areas

a. Sterile/nonsterile supply storage areas will be kept clean and uncluttered. The lower shelves in storage areas will be solid and will have at least eight inches of space between the floor and bottom shelf to allow for proper cleaning under the shelving unit. This space will allow access for cleaning to avoid contamination of medical supplies. Top shelves and contents will be arranged 18 inches from fire detecting or extinguishing systems that are installed in or suspended from the ceiling. Shelving must be at least two inches from outside walls to avoid condensation and contamination of supplies. Shelving must be kept clean and dry. Storage areas must be kept free of dust, dirt, moisture, insects, rodents, and other vermin.

b. Supplies must be stored so as not to crush, bend, compress, or puncture the packaging or otherwise compromise the sterility of the contents.

c. Medical and surgical supplies will not be stored next to or under sinks or ice machines, under exposed sewer or water pipes, or in any location where they can become wet or compromised.

d. Supplies will not be stored directly on the floor, on windowsills, or in areas other than designated shelving, counters, or carts.

e. Exterior shipping cartons and corrugated boxes will be removed prior to material entering SPD or designated using unit storage areas. Shipping cartons or corrugated boxes will not be used as dispenser bins or storage containers.

f. Sterile items must be stored in carefully controlled conditions that are protective of extremes in temperature and humidity. Temperatures must be maintained between 65 and 72 degrees Fahrenheit, and humidity will be maintained between 35 and 75 percent.

g. Sterile storage areas must remain locked and must have carefully controlled traffic patterns with limited access.

4. 1004 Additional Storage Locations. Storing, handling, and distributing products are vital parts of the patient care function. In addition to the clean/sterile storage area, SPD supplies and equipment are stored in areas including breakout and bulk.

a. Breakout. Purchased medical supplies are received into SPD in a breakout area. In the breakout area, supplies are removed from their outer shipping containers and corrugated boxes before being admitted into the clean/sterile storage area. Proper separation of clean and dirty must always be maintained. Environmental controls are not the only factors that ensure high-quality supplies. As supplies are received in the breakout area of SPD, shipping containers are inspected to ensure that no damage has been done during transport.

b. Bulk Storage. This is an area where excess items are stored until space is available in the clean/sterile storage areas. No broken shipping containers will be left in this area. In addition, no dispensing of supplies will be done from this area. This area will not be used for excess items no longer needed in the medical center.

PART 11. EQUIPMENT CONTROL

1. 1101 EQUIPMENT CONTROL. Each VA medical center has a procedure for tracking medical equipment. AEMS/MERS is an equipment tracking and preventative maintenance program available through the medical center's Decentralized Hospital Computer Program (DHCP). AEMS/MERS provides information on equipment including acquisition history, warranty information, repair history, and the like. Patient care equipment will be tracked and monitored consistent with the latest edition of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) "Accreditation Manual for Hospitals."

2. 1102 PATIENT CARE EQUIPMENT

a. Preventative maintenance of equipment related to patient care equipment is a particularly important part of patient safety. The inspection process begins when the equipment is received in the decontamination area. During the cleaning process, electrical cords are visually inspected, and any obvious external damage is reported to the preparation/ decontamination supervisor or the Chief, SPD.

b. SPD also plays a role in other aspects of the preventive maintenance program including electrical safety inspections. SPD works with the facility Biomedical engineering program to understand the requirement of the technical preventive maintenance program and inspection schedule. After the equipment has been cleaned, equipment due for an electrical safety inspection is taken to the biomedical engineering section. Battery charging and superficial operating checks complete the preventative maintenance activity.

(1) Routine Operator Maintenance. Clinical staff is responsible for the safe use of patient care equipment. They should immediately identify any equipment issued by SPD that is found to be defective or inoperable. A clinical staff member will call SPD for replacement of the defective unit. The biomedical engineering section then processes the defective unit through decontamination before assessment.

(2) Operating Instructions. Copies of patient care equipment operating instructions are kept on file in SPD.

(3) Storage/Distribution Procedures. Most mobile patient care equipment is stored in and issued through SPD. Equipment is kept in operating condition and ready for issue. All equipment with rechargeable batteries is plugged into electrical outlets. Components such as cables, probes, and tubing are also kept ready for issue. Equipment is issued upon request to meet patient care needs.

3. 1103 SECTION EQUIPMENT. Operating procedures for all SPD section equipment (e.g., sterilizers and washers) can be found in section 8 of the SPD Desk Guide.

a. Preventative Maintenance. Preventative maintenance includes inspection, testing, and minor repairs or replacement done on a schedule. Preventative maintenance is a joint effort between SPD, Engineering/Facilities Service, and manufacturers' service technicians.

(1) SPD is responsible for daily inspection of section equipment. Sterilizers, for example, are monitored for efficiency through chart or printout data and gasket integrity. Soap consumption and the condition of the items washed are monitors of automatic washers.

(2) Detailed recorded maintenance on SPD section equipment is scheduled either by Engineering/Facility Service or manufacturers' service representatives. These more detailed inspections involve electrical function, pressure testing, and EtO safety. Records of this work are kept on file in the biomedical engineering section.

b. Routine Operator Maintenance. An equipment operator's maintenance responsibilities are twofold: cleaning and equipment observation. The SPD operator monitors charts, printouts, and gauges, ensuring that they are functioning within normal limits. Additionally, parts such as door gaskets, soap pumps, automatic doors, and audio/visual alarms are observed for working readiness as per manufacturers' instructions.

c. Operating Instructions. The manufacturer's operating instructions will be located near each piece of equipment. These instructions can be found in section 8 of the SPD Desk Guide. Because of the complexity of SPD processing equipment, the operating instructions are adhered to without deviation.

PART 12. EQUIPMENT TRACKING

1. 1201 SCOPE. This part establishes requirements for tracking of patient care equipment "issued by SPD."

2. 1202 LOCATOR AND USAGE RECORDS

a. An ongoing locator and usage record will be established for each piece of patient care equipment issued by SPD. Such records help to determine if maximum usage and longevity are realized from equipment and indicate the current location of equipment in use. Records will include, but will not be limited to, the following information:

(1) Type of Equipment.

(2) Preventative Maintenance Number.

(3) Serial Number and/or Nomenclature as Listed on CMR (Equipment Inventory List).

(4) Issued To (Using Area Location).

(6) Issued by (Name).

(7) Date Returned.

(8) Operational Remarks.

b. Records will be kept current and maintained in SPD for the life of each piece of equipment. Anyone who removes equipment from the SPD section during non-operation hours will record this information on the After Hours Sign-Out Log in SPD. (Refer to part 1, paragraph 4.104 of this handbook for "Hours of Operation/After Hours Acquisition.")

c. A system will be devised locally to ensure that SPD is notified when equipment is transferred with the same patient to another area of the facility. Equipment control records will be promptly adjusted. All equipment issued by SPD must be returned to SPD for decontamination, disinfecting, and/or sterilization prior to use by another patient. When equipment is referred for repair or preventative maintenance, records will be annotated.

d. Where possible, equipment control data should be maintained through the use of barcoding via automation capabilities.

PART 13. QUALITY CONTROL

1. 1301 STERILIZATION RECORDS AND CONTROLS

a. A six-digit control number will be assigned for each sterilizing cycle. The first digit will identify the numerical designation of the sterilizer being used. The second, third, and fourth digits will indicate Julian calendar day of the year, i.e., 001 through 365 days. The fifth and sixth digits will indicate the number of times the sterilizer operated during a 24-hour period.

b. Each package or item terminally sterilized will be labeled prior to sterilization with the common name of the package contents or item and initialed by the employee who prepared the package or item for sterilization. All sterilizer cycles will be recorded, and contents of the load will be listed as to general category.

c. The control number and expiration date will be affixed to each package or item intended for use as a sterile product after the mechanical and chemical indicators have been checked after sterilization. Markings will not be made directly on the wrapper by either ball point or felt tip pens as they may puncture or strike through the wrapper and contaminate the contents. A mechanical labeling device is recommended.

d. A register will be established for all sterilizing equipment without an automatic recording device. The sterilizer operator will record the following information for each sterilizing cycle:

(1) Sterilization date.

(2) Time cycle was started.

(3) Time sterilization phase began.

(4) Sterilization temperature.

(5) Actual length of sterilizing cycle at desired temperature (exposure period).

(6) Remarks (e.g., condition of load, sterilizer breakdown).

(7) Signature of sterilizer operator.

e. For all sterilizers equipped with a recording device, the appropriate chart or digital printout will be examined and signed by the sterilizer operator after each cycle, before any items are removed from the sterilizer to verify adequate temperature and duration of exposure. Sterilizer malfunctions or suspicious operation, as indicated by the recording device, will be reported immediately to the Chief, SPD, who will make the final determination on the use of that sterilizer, initiate an appropriate request for service, and implement reprocessing routines for the load in question, if necessary.

f. For all sterilizer loads, the control number assigned and a register of contents as to general category (e.g., linen packs, instruments, respirator care supplies) will be maintained. This register will be critical in the event that a recall is necessary due to sterilizer failure. This register will be maintained, along with other sterilization records, for a period of 36 months.

g. Sterilizer malfunctions or suspicious operation, as indicated by the recording device, will be reported immediately to the Chief, SPD. The Chief, SPD, will make the final determination on the use of that sterilizer, initiate an appropriate request for service, and implement reprocessing routines for the load in question.

2. 1302 STERILIZATION PROCESS CONTROLS. All reusable medical/surgical devices used for patient care (direct or indirect) should be sterilized in the SPD section. **The Chief, SPD, is responsible for all sterilizers and sterilization in the medical center and clinics**. Reusable devices are items that are manufactured for reuse, or for which the manufacturer has provided specific written resterilization instructions. If, for some reason, (due to staff, limited equipment, required short turn-around time) sterilizers are located in other sections of the medical facility, they will be monitored mechanically, chemically, and with biological indicators. All records will be kept for 36 months (this includes all sterilizers in the medical facility used in conjunction with patient care, e.g., lab, dental). A report of all tests and results will be submitted through the Chief, SPD, to the Infection Control Committee monthly.

3. 1303 STERILIZER TESTS. A Bowie-Dick type test to determine adequacy of air removal from chamber and porous load will be performed daily for each pre vacuum (high vac) steam sterilizer. The test results will be recorded on the sterilizer-recording chart. If commercially prepared test products are used, the test will be carried out according to the written instructions of the manufacturer of the system used. In the absence of commercial products, test packs will be prepared locally (refer to directions in part 7, Item Preparation).

4. 1304 BIOLOGICAL MONITORING

a. A standard operating procedure for biological monitoring of all sterilizers in the medical center will be established by the Chief, SPD, as outlined in part 3, Infection Control, of this handbook. All records will be retained for 36 months.

b. When a positive biological test result is obtained, the biological indicator will be immediately submitted to the microbiology laboratory for a presumptive organism identification. This helps to determine if the living microorganism is the indicator test microorganism (indicating inadequate sterilization conditions) or an accidental contaminant that could have been introduced after the load was removed from the sterilizer. If spores are not killed in routine spore tests, the proper use and function of the sterilizer will immediately be checked. All items processed in a sterilizer since the last negative test will be recalled for a positive test. The sterilizer in question must immediately be rechallenged with biological indicators. If spore tests remain positive after proper use of the sterilizer is documented and an operational inspection has been performed, use of the sterilizer will be discontinued, and it will be serviced.

c. Positive biological indicator results will be reported immediately, in writing, by the Chief, SPD, to the Chief of Staff; Chief, Surgical Service; the Service responsible for the SPD Section; and the Infection Control Committee. The report will include the time and date of the questionable sterilizer cycle; description of the sterilizer and load, with reference to the appropriate load control number; time and date of notification of positive results; laboratory identification of the organism; and any other pertinent information. The Chief, SPD, will make recommendations to the Chief of Staff; Chief, Surgery Service; and the service responsible for the SPD section for further action as considered appropriate or necessary. In all cases, the sterilizer in question must immediately be rechallenged with biological indicators.

d. Not later than the 10th day of each month, a written report of biological spore tests conducted on all sterilizers during the previous month will be submitted to the medical facility Infection Control Committee by the Chief, SPD. This report will include the total number of biological tests and controls conducted on each sterilizer and the results of that testing. The Chief, SPD, is responsible for biological monitoring and reporting on all sterilizers involved in processing any item used for direct or indirect patient care. For sterilizers that are located in areas other than SPD, the Chief, SPD, will provide the necessary training and assistance for performing the monitoring and reporting described above.

5. 1305 QUALITY CONTROL RECORDS. Quality control measures must be documented. All sterilizer recording charts, digital printouts, registers, biological and Bowie-Dick test results, reports, and other associated quality control documentation will be maintained for at least 36 months. The Chief, SPD, will ensure that all equipment used in the SPD section functions, and all patient care equipment assigned to SPD is scheduled for routine preventative maintenance.

NOTE: Some states require that sterilization records be maintained for longer than 36 months. You must be aware of your state's requirements for retaining these records.

6. 1306 QUALITY ASSURANCE AND BENCHMARKING

a. Quality assurance and benchmarking are very important components of the SPD program. It is required that critical elements be identified and that benchmarking standards be determined. Areas of consideration for quality assurance would include:

(1) Implantable Devices.

(2) Complete Instruments and Sets.

(3) Instruments in Proper Working Order.

(4) Stock Levels/Fill Rates.

(5) Case Cart Accuracy.

(6) Compliance with Personal Protection Equipment (PPE) Requirements.

b. Continuous Quality Assurance Monitors should always include:

(1) Biological Monitoring.

(2) Mechanical Monitoring.

(3) Chemical Monitoring.

(4) EtO Personal Exposure Monitoring.

PART 14. GLOSSARY

The following terms are defined as they relate to SPD:

1. Aeration. Exposure to the free actions of circulating air with the use of a mechanical aeration device utilizing filtered air at elevated temperatures.

2. Aerobic. A microorganism that needs the presence of free oxygen or air to live and grow. Staphyococci, pneumococci, and tubercle bacilli are examples of aerobic bacteria.

3. Anaerobic. A microorganism that lives and grows in the absence of free oxygen or air. Clostridium tetani (tetanus/lockjaw) and CI welchii (gas gangrene) are examples of anaerobic bacteria.

4. Anatomy. The study of the structure of the human body.

5. Antiseptic. A mild disinfectant used on the skin and mucous membranes to lower the count and inhibit the growth of bacteria.

6. Aseptic. Freedom from infection; the absence of microorganisms that cause disease.

7. Aseptic Technique. Performance characterized by precautions for the constant exclusion of microorganisms. This means a method of working while maintaining a sterile area by avoiding contact with anything that is not sterile.

8. Autoclave. A common term applied to sterilizing by steam under pressure that kills all bacteria including spores.

9. Bactericide. A substance that kills bacteria but not spores.

10. Bacteriostasis. The stopping or inhibition of bacterial growth and reproduction.

11. Benchmarking. To measure a customer service program according to specified standards in order to compare it with and improve one's own product.

12. Bioburden. The number of microoganisms on a contaminated object.

13. Biohazardous Material. Items which may be contaminated with microoganisms with the potential to cause infection.

14. Biological Monitoring/Indicator. A measured amount of miroorganisms on a carrier used to show that sterilization conditions were met. The microorganisms must be highly resistant to the mode of sterilization being used. Commercially prepared biological tests should be utilized when available.

15. Bowie-Dick Type Test. This test is used to determine the adequacy of air removal from an empty sterilizer chamber. This test will be performed daily for each pre-vacuum (high vac) steam sterilizer. The test results will be recorded on the sterilizer recording chart. If commercially prepared test products are used, the test will be carried out according to the written instructions of the manufacturer. In the absence of commercial products, test packs will be prepared locally (refer to directions in part 13, Quality Control, paragraph 1304 of this handbook).

16. Certified/Certification. The state or process of achieving the level of knowledge to pass a written examination signifying a level of expertise and maintaining this level of knowledge through continuing education units (CEUs).

17. CEUs. See Continuing Education Units.

18. Chemical Indicator/Chemical Indicator Tape. A physical/chemical device used to monitor one or more parameters of the sterilization process. This is to assure that factors such as packaging, loading, and/or sterilizer functioning do not prevent sterilization by means of a characteristic color change. The chemical indicator usually consists of a sensitive chemical or ink dye, the sensitivity of which may vary from product to product.

19. Chemical Monitoring. A device used to monitor certain parameters of a sterilization process by means of a characteristic color change, e.g., chemically treated paper strips and pellet-sealed in a glass tube.

20. Chief, SPD. The program official responsible for management of the supply, processing, and distribution (SPD) functions within the medical center or clinic.

21. Clean. Free from dirt, stain, or impurities.

22. Consignment. A vendor maintains a portion of the primary inventory on the shelves and bills the medical center once a month for items used during that period. Consignment is considered a "no cost" inventory program because the medical center pays nothing until items are used.

23. Continuing Education Units (CEUs). Credits received for completing training and attending seminars directly relating to a profession. One CEU is generally given for each hour of training or seminar attendance.

24. Crash or Code Carts. Specialty carts used in emergency situations to revive victims from respiratory failure or cardiac arrest.

25. Commodities Standardization Committee. The committee that will review all requests for the purchase of any new expendable medical supplies prior to purchase action being taken.

26. Containerized Sterilization System. A specially designed container system (pre-formed rigid container) for sterilization, transportation, storage, and presentation of surgical instruments. When sealed, the container assembly allows penetration of air and steam (or gas) into and out of the container for sterilization of its contents.

27. Contaminated. The presence of a pathogenic agent on a body surface or inanimate article, or in a substance. The state of being soiled or rendered unsafe for use by contact with infectious material.

28. Contamination. The act of making something impure or unclean, especially the introduction of infectious material or disease germs into or onto normally sterile objects.

29. Decontamination. The destruction or removal of living organisms to the highest level possible, but not necessarily to zero.

30. Decontamination Area. The area of SPD where instruments, supplies, and equipment are decontaminated or rendered safe for handling by reducing the bioburden.

31. Detergent. Chemical substance or mixture of substance that has cleansing action because of a combination of properties, including lowering of surface tension, wetting action, emulsifying, dispersing actions, and foam formation.

32. Detergent Germicide. A solution containing a detergent for cleansing purposes and a germicide for antimicrobial action.

33. Dirty. Soiled as with dirt; unclean.

34. Disaster Carts: Carts stocked with medical supplies needed for use in emergencies (internal/external disasters) such as a large traffic accident, bombing, or flood. These supplies should be stocked on a cart that can be easily transported to the scene of the disaster. Transportation of these disaster carts should be conducted in a manner so as not to compromise the medical supplies contained within the cart. It is recommended that the contents of disaster carts be reviewed and updated as needed or, at minimum, on an annual basis.

35. Disinfectant. A chemical agent that kills or inactivates vegetative bacteria, fungi, and some viruses, but not spores.

36. Disinfecting. The process, chemical or physical, which removes, controls, or destroys the growth of microorganisms. While chemical disinfection rapidly kills vegetative cells, it may not kill all spores and viruses.

37. Disinfection. Destruction of the growth of microorganisms**.** While chemical disinfection rapidly kills vegetable cells, it may not kill all spores and viruses.

38. Distribution Area. The area of SPD responsible for maintaining and disseminating supplies, instruments, and equipment throughout the medical center.

39. Dust Cover. An additional protective post sterilization overwrap used to assist in maintaining the sterility of a product by protecting it against the environment. Usually made of plastic 2-3 mils thick, the dust cover does more than protect from dust; it also serves as a barrier to contaminants such as moisture, lint, or vermin.

40. Exchange Cart System. The exchange cart system, like the par-level restocking system, has pre-set levels that have been established by the user and the SPD technician. In the exchange cart system, two identical carts are stocked with supplies. Once the levels of these carts have been established, one cart is placed in the user area and one in SPD. On a regular basis, the cart in the user area is returned to SPD and the identical (fully stocked) cart in SPD is exchanged in its place.

41. Expiration Date. The date that is calculated by adding to the date of sterilization the shelf life of a sterilized product (see Shelf Life), i.e., 30 days for breathable packages such as muslin and non-woven material and 1 year for non-breathable packages such as peel packs and dust covers.

42. External Chemical Indicators. A strip of the appropriate sterilizer indicating tape must be affixed externally to each package prior to terminal sterilization. This indicator tape, label, or legend indicator visually denotes that the package has been exposed to the physical condition of a sterilizing cycle, but will not be considered evidence of sterility. The indicator must be examined after sterilization to make sure it indicates that the item has been processed

43. Flash Sterilization. The process of sterilization without the benefit of a package or method of maintaining the sterility of the device. Examples include the operating room sterilizers and the Steris chemical sterilizer.

44. Gas Chromatography. A monitor that is specifically used for a particular gas that will record the level down to at least one hundredth (.01) parts per million (ppm). This type of instrument is used in SPD to monitor Ethylene Oxide and must be equipped with a gas mask.

45. Germicide. Germ-killing agent.

46. Gross Soil. Contamination with large amounts of chemical or biological material that may pose a hazard to the environment during transport. This soil must be reduced before leaving the point of use.

47. Impervious. Those wrapping materials that do not permit the free passage of air, water, or other contaminants through their walls under normal handling and storage conditions.

48. Implantable Device. A device that will be surgically implanted and totally contained in the body. Examples: Orthopedic hardware items such as pins, screws, nails, rods, and hardware used in total joint system replacement; prosthetic heart valves; central nervous system reservoirs and drains; and breast prostheses. Drains and tubes used temporarily after surgery are excluded.

49. Infection. The invasion by pathogenic microorganisms of a bodily part in which conditions are favorable for growth, toxin production, and tissue injury.

50. Infectious Disease. A disease resulting from the presence and activity of a microbial agent.

51. Infectious Microorganism/Agent. A pathogenic microorganism. Anything that causes disease, especially microorganisms such as bacteria and fungi.

52. In-Service Education. Class or seminars, which are conducted to educate employees about current trends and practices in their professions.

53. Internal Chemical Indicator. Tape, card, or integrator placed within a package in order to monitor one or more parameters of the sterilization process to assure that factors such as packaging, loading, and/or sterilizer functioning do not prevent sterilization by means of a characteristic color change. The chemical indicator usually consists of a sensitive chemical or ink dye, the sensitivity of which may vary from product to product.

54. Just-In-Time (JIT) Delivery. A concept where costly inventories are reduced by eliminating the primary inventory. JIT allows secondary inventories to be stocked on a regular basis by providing medical supplies just-in-time. This system works best when needs can be easily and accurately forecasted.

55. Liquid/Cold Chemical Sterilization. The submersion of a device in a chemical solution that will render a device free of all microbial life. Examples include glutaraldehyde, phenolic compounds, alcohol, quatenary compounds, and iodine. There is no present method available that allows the user to microbiologically test the efficacy of a liquid chemical sterilization process within the healthcare facility. Liquid chemical and cold liquid sterilization processes, therefore, may be employed for high level disinfection only. The manufacturer's recommendations for the solution to be used will be followed. Terminal sterilization by this method is not authorized.

56. Load Control Number. A combination of numbers by which a particular group of hospital-sterilized products may be traced to a particular sterilization process.

57. Material Safety Data Sheet (MSDS). Information required by OSHA, provided by the manufacturer, and listing the contents of a chemical, any hazards, precautions, and handling instructions needed when using or being exposed to the agent. First-aid requirements are also listed. These sheets must be readily available for all chemicals that SPD staff may come in contact with in normal performance of their duties.

58. Mechanical Monitoring. Devices built into a sterilizer, such as indicating thermometers, recording thermometers, pressure gauges and automatic controls, which are used to assist in identifying and preventing malfunctions and operational errors.

59. Microbiology. The study of microorganisms.

60. Microorganisms. A tiny living organism, invisible to the naked eye and only visible by a microscope.

61. Muslin. An all-cotton, 140-thread-count fabric used as a sterilization wrapping material.

62. Nonpathogenic Microorganisms. Microorganisms which do not produce disease.

63. Non-Sterile. The presence of microorganisms.

64. Nosocomial. Denoting a new disorder (not the patient's original condition) associated with being treated in a hospital, such as a hospital-acquired infection.

65. Nurse Servers. Nurse servers are self-contained storage units that are located at each patient care room. These units serve a dual purpose in that one side is used to stock sterile/clean medical supplies and the other is for soiled medical supplies. These servers have doors on both sides (one in the hallway and one inside the patient room). These doors will remain locked at all times when not in use to prevent unauthorized individuals from having access to medical supplies and to prevent injury to patients from contents within. Medical supplies stocked in these servers should be standardized and reviewed periodically to reduce waste, contamination, and excess stock.

66. Opportunists. Bacteria that do not normally invade the tissue but are capable of causing infection or disease if introduced mechanically into the body.

67. Organism. An individual form of life, such as a plant, an animal, a bacterium, a protist, or a fungus; a body made up of organs, organelles, or other parts that work together to carry on the various processes of life.

68. Orientation. Introductory instruction concerning SPD functions for incoming employees.

69. Pathogenic Microorganisms. Any microorganism that produces infectious disease. They are capable of invading healthy tissue by their ability to produce toxins.

70. Personal Protective Equipment. Protective equipment, such as approved head and hair coverings, face shields, safety glasses/goggles, long cuffed rubber/vinyl decontamination gloves, impervious gowns, and shoe covers that are utilized to protect the employee from the environment.

71. Physiology. The study of the function of the human body.

72. Post-Sterilization Wrap Procedures. Any or all of the activities taking place after sterilization of materials or equipment.

73. Preparation Area. The area of SPD where clean supplies, instruments, and equipment are assembled and sterilized.

74. Prime Vendor. A single vendor serves as distributor for a portion of the SPD primary inventory, regardless of brand or manufacturer. They provide next-day delivery that allows SPD to greatly reduce the amount of stock on hand.

75. PROGRESS. Program to Guide the Reinvention of Enhanced Supply Support. This is also referred to as Total Supply Support. This function should be centralized as much as possible in order to avoid duplication and make sure excess stock is not maintained. One staff should manage all supplies in the medical center.

76. Sanitization. The act of making environmental conditions favorable to health. It frequently involves a process that reduces the number of microorganisms to a level which is considered safe for human use.

77. Sepsis. The presence of pathogenic organisms and their toxins in the blood or tissues.

78. Shelf Life. The period of time during which sterility of a product is assumed to be maintained or the product remains in safe condition for use.

79. Soiled. Devices that are contaminated and must be cleaned before use.

80. SPD Level I Training. This is a mandatory training to be completed by all SPD and other staff involved in the supply, processing, and distribution of medical/surgical supplies in medical centers and clinics. After completing this training, the members may complete Level II training and become a Certified Medical Supply Technician. A training guide (Level 1: Training Instructor's Manual, TP-90-3) is to be used.

81. Spores. A bacterium in a dormant state that has a thick wall and is protected from adverse environments. A spore is very difficult to destroy. Sporacides or sterilizing agents are necessary to kill spores.

82. Sterile. The state of being free from all living microorganisms.

83. Sterility. The state attained by sterilization or chemical means/agents.

84. Sterilization. The process of destroying all microorganisms on a substance by exposure to physical, or chemical means/agents.

85. Stockless. A system where there is no primary inventory. Stock is delivered by vendors on an as-needed basis, prepackaged, 2-3 times per day, 7 days a week.

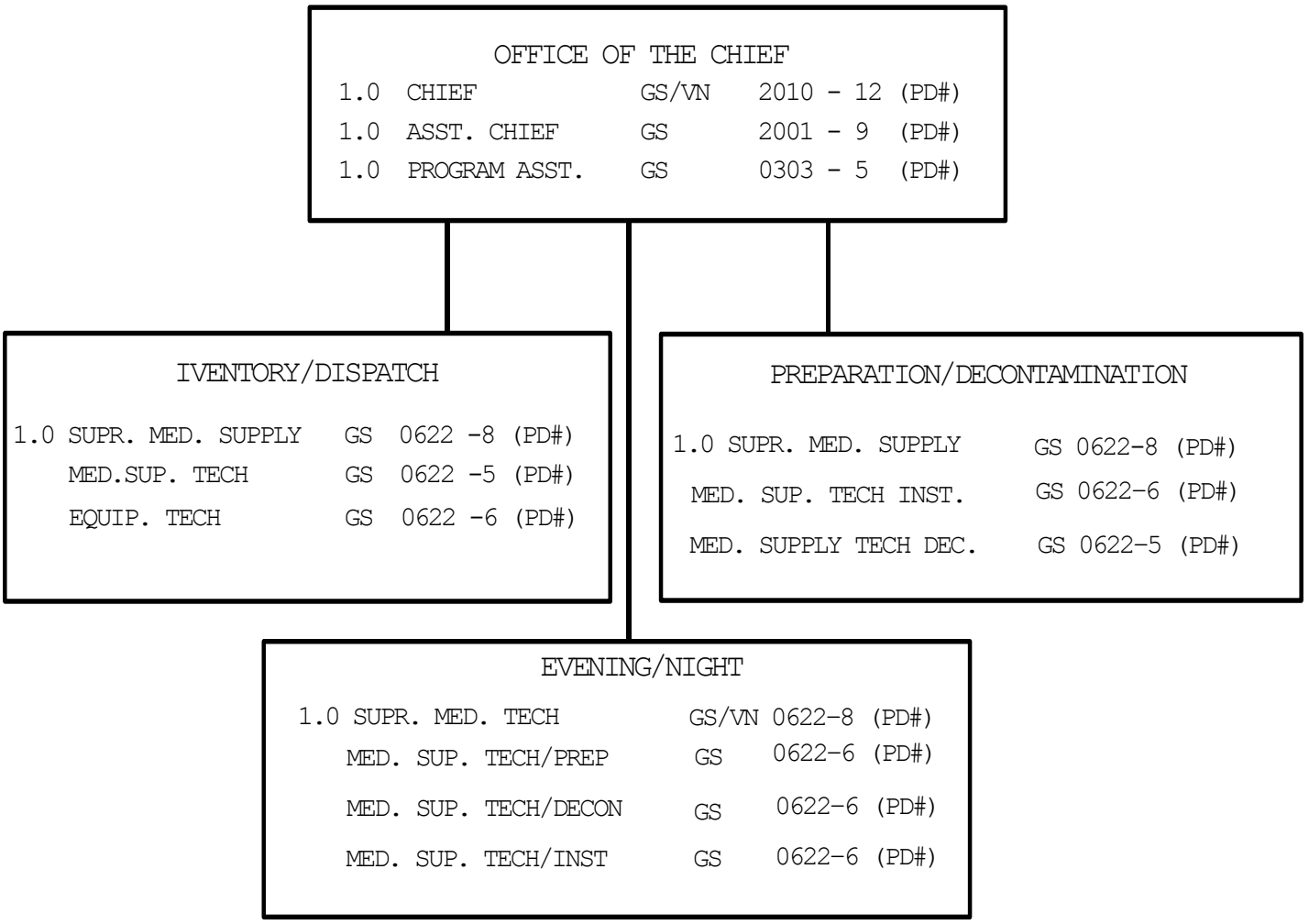
86. Terminal Sterilization. The final sterilization process prior to issuance of sterile supplies for consumer use.

87. Total Care Support. The support provided to the user of supplies and service, which SPD provides. This should include as much as possible of all inventory management, distribution of supplies and equipment, and decontamination and sterilization of reusable medical/surgical devices. This may include other services such as processing of mail, laundry, patient transport, and other related functions.

88. Total Supply Support. See Total Care Support.

PART 15. ILLUSTRATION

CHIEF, SUPPLY, PROCESSING, AND DISTRIBUTION



Please replace this organization chart with your local one.